St Luke's Hospice Research Policy and Procedures

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RE-APPROVAL DATE	

Version History

VERSION	DATE ISSUED	ISSUED TO	BRIEF SUMMARY OF CHANGES
1			New policy
2	23/02/2023		Updated risk framework – Appendix 4
3	21/01/2025		Updated throughout in light of expanded research team/activity, research register and KPI's.

Related Policies and Procedures

Clinical Audit and Service Evaluation Policy and Procedures	Information Governance Policy and Procedures
Incident Management Policy and Procedures	SLHSOP001- Informed Consent SOP
SLHSOP002- Archiving SOP	SLHSOP003 – Documenting source data in medical notes SOP

Clinical Audit & Service Evaluation Policy Version 2. August 2024	SLHSOP004- Maintaining a study site-file SOP

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Please note that the intranet version of this document is the only version that is maintained. Any printed copies should be viewed as "uncontrolled" and as such may not necessarily contain the latest updates and amendments.

Contents

Introduction

Clinical services and education are well-established themes in palliative medicine practice; research is the third theme of increasing importance. This synthesis of clinical work and research is written into one of St Luke's Hospice's three charitable objectives:

> "St Luke's objectives are to relieve sickness and assist in the treatment and care of persons suffering from mental or physical illness of any description and in particular…by conducting, exploring or encouraging research and the evaluation of improvements in the care of the terminally ill person and that person's carers and relatives, and to disseminate the useful results of such research."

Building on this objective, SLH has a research vision which is used as the basis of our ongoing Research Strategy:

> "St Luke's will become a research-leading hospice, capturing funding and drawing on well-established processes to generate its own research output, driving the local, national and international research agenda, and becoming a centre recognised for innovation – with an overriding aim of producing demonstrable benefits to the people of Sheffield."

As such, this policy should be read alongside the Research Strategy.

Health research conducted in the UK is subject to strict regulations and guidance, which is overseen by the Health Research Authority. St Luke's will conduct research to the highest of legal and ethical standards, with clear and transparent decision-making processes and a robust governance structure.

Abbreviations

Clinical Audit and Research Group – CARG
General Data Protection Regulation – GDPR
National Research Ethics Service - NRES
NHS Health Research Authority – HRA
Research Ethics Committee - REC
St Luke's Hospice – SLH/St Luke's
Clinical Research & Development Committee (formerly Research Committee)- CRDC
Ecclesall Road South (formerly Clifford House) - ERS
Head of Research- HoR
Research & Innovation Manager- R&IM
Research & Innovation Office - R&IO

What is Research, Clinical Audit, Service Evaluation and Quality Improvement?

Research, clinical audit, service evaluation and quality improvement (QI) are all approaches to gather and interpret information for different purposes using similar methods to influence quality.

Research uses scientific methods to generate new knowledge by addressing clearly defined questions with systematic and rigorous methods, largely requires funding and takes a significant amount of time.

Clinical audit measures a service's activity against a "gold standard" so stakeholders and patients know their service is doing well, and where there could be improvements. The outcome of an audit can highlight where improvements are needed, it is often the first step in the QI process,

Service evaluation Service evaluation is broad in remit. It aims to describe how well a service is achieving its intended aims. It usually has the purpose of evaluating an already established service, or the introduction of a change or new service.

Service evaluation may be used to determine whether a service is fit for practice and will usually be used to inform local decision-making where particular issues need solving.

Quality improvement (QI) projects build upon clinical audit and service evaluation to improve what a clinical service is doing. QI does not seek to create generalisable knowledge, rather it generates several lessons as to what actually works and does not work and why in the specific area you want to improve. In QI, the measurement framework is not about pre- and post-intervention (which is commonly the case in research), but continuously measuring the metric of interest that needs to be improved and, identifying multiple interventions based on learning from Plan-Do-Study-Act (PDSA) cycles to generate sustained improvement. In addition, in QI the goal is to *improve* rather than to *prove*, which means the data can be 'just good enough' rather than perfect.

Clinical audit, service evaluation and quality improvement are approaches which relate to the internal working of an organisation or group of organisations, and are regarded as a normal part of practice. For more information, please refer to the Clinical Audit and Service Evaluation Policy and Procedures. Research, however, seeks to gain knowledge that might apply more widely.

Key criteria below to consider when deciding if your project is research, clinical audit, service evaluation or quality improvement.

	Service Evaluation	**Audit**	**Research**	**QI**
Overall aim	To describe the quality of the current service	To measure clinical practice against a standard	To generate new knowledge/add to the body of knowledge	To continuously improve the quality of services and outcomes
Initiated by	Service providers	Service providers	Researchers	Service users/Researchers
Involves a new treatment	No	No	Sometimes	Sometimes
Randomisation	No	No	Sometimes	Sometimes
Allocates patients to treatment groups	No	No	Sometimes	Sometimes

The decisions related to which category a proposed project falls into can be supported by the St Luke's Clinical Audit and Research Group (CARG), which provides support, information and guidance. This group, with the support of the Clinical Research & Development Committee (CRDC), has the final say in determining what type of activity proposed projects are. Please see the Clinical Audit and Research Group section below for more information.

Research Policy Objectives

This policy and its procedures relate to research activities only, from the conception of an idea through to final reporting and dissemination of findings. This will ensure that regulatory requirements are fulfilled and that SLH has an accurate, auditable record of research activity being undertaken on its premises and/or about its staff, patients or clients. It will ensure that any research carried out within the organisation is relevant, appropriate, ethically sound, meets legal safeguards and is conducted to the highest scientific standard.

Accountability and Responsibilities

The Medical Director & Clinical Lead for Programme Development is the executive lead for research and will oversee the effectiveness of this policy and associated procedures, providing assurance to the Board of Trustees and Chief Executive.

The Head of Research (HoR) (formerly Research Lead) and the Research & Innovation Manager (R&IM) based in the Research & Innovation Office (R&IO) at SLH are responsible for ensuring all research activities conducted within SLH comply with regulatory requirements and follow this policy and its associated procedures. This includes maintaining the Research Register and, where necessary, ensuring secure storage of site files of research documents. Going forwards in this document

it is the Research & Innovation Office (R&IO) that will be referenced rather than an individual.

The Head of Research is also the Chair of the Clinical Audit and Research Group. The R&IO is responsible for ensuring research projects are discussed and considered at every meeting and updates are provided on a regular basis. The R&IO will provide updates to the Clinical Research & Development Committee (CRDC) in accordance with the Research Governance Framework (Appendix 1). The Head of Research retains responsibility for these processes set out in this document but will deputise the day-to-day function to the R&IO.

The R&IO is responsible for ensuring all studies are registered in the St Luke's Hospice Research Register which records all governance processes required for an individual study to receive SLH Research Capacity & Capability (C&C) and commence activity in the hospice. No study will commence activity without written confirmation of C&C.

The Clinical Quality and Risk Lead is responsible for working with the R&IO to facilitate the Clinical Audit and Research Group, and provide support to the R&IO and staff requiring information about audit, service evaluation and quality improvement projects upon request to facilitate CARG meetings.

The CARG is responsible for ensuring all research projects operate within an appropriate governance framework and that SLH is not exposed to unmitigated or uninsured risk. The group will support the delivery of high-quality evidence-based care, will provide reports and updates to SLH's governance groups as required to provide assurance to the Medical Director and Clinical Research & Development Committee. For more information on the specific functional responsibilities and activities of the CARG, please refer to its Terms of Reference in Appendix 2. Before any research can take place at SLH, it must be approved by the CARG.

All staff undertaking any research project will be referred to forthwith as "researchers". Researchers are responsible for ensuring their proposals comply with the requirements set out in the St Luke's Hospice Research Management Approval Form (Formerly Study Checklist) as found in Appendix 5. They are also required to provide updates to the R&IO/R&IM regularly and upon request, and may be required to present their study to SLH governance groups, papers to patient, etc. It is expected that researchers will raise initial enquiries with the R&IO.

Line managers are responsible for providing support to researchers in their teams, liaising with the R&IO where appropriate, and therefore contributing to SLH's vision of becoming a research-leading hospice.

Regulatory Requirements

The NHS Health Research Authority (HRA) has legally-mandated responsibility for all health-related research undertaken in the UK, delegating that responsibility to organisations and their respective systems. This ensures that all research meets the requirements of being ethical, legal and robust. The requirements of the HRA and their delegated organisations mandate a clear audit trail, record-keeping processes regarding research conduct. It is expected that most research taking place at SLH will be covered by HRA requirements.

NHS trusts typically have a research department and follow a standardised national process for approving research on site. SLH, as an independent unit, is outside of NHS systems. Nevertheless, NHS processes provide an example of good practice and therefore SLH R&IO will align with these governance processes

Where research involves personal identifiable information, sensitive data, human tissue, the NHS, prisons, social care or other particular specialist or vulnerable groups, additional approvals may be required. Examples include NHS Research Ethics Committees ("REC"), the Medicines and Healthcare Products Regulatory Agency (MHRA) or the Confidentiality Advisory Group ("CAG").

The HRA web site (https://www.hra.nhs.uk) has detailed information including a decision tool to help determine whether a project is research as defined by the UK Policy Framework for Health and Social Care Research, and what approval(s) may be needed. This tool can be found here: http://www.hra-decisiontools.org.uk/research/.

It is expected that SLH will be invited to take part in research that is outside the remit of the HRA. Such studies are still likely to have been assessed for methodological rigor by the study sponsor, which will usually be a university ethics committee or NHS trust or funding body (NIHR). (Note that a sponsor is the organisation leading the research, and not necessarily the funding organisation).

In some cases, external approvals may not be needed. Such studies will be considered on a case-by-case basis by the CARG and/or SLH CRDC.

Intellectual Property

The sponsor must be clear whether their study could potentially lead to the generation of intellectual property rights (IPR). Where new IPR could potentially be generated, SLH expects clarity on how these IPR have/will be protected. All queries relating to IP at SLH will be discussed with the executive representative at CARG and escalated as appropriate.

Applying for and Evidencing Regulatory Approval

Where regulatory approval is required, researchers typically apply via the Integrated Research Applications System (IRAS). Whether studies need to be reviewed by other regulatory bodies will depend on the study type, and will be identified via IRAS once the research project's category has been identified. The application forms for the submissions to the IRAS national system capturing all the necessary information for the relevant approvals.

Guidance on completing the form and supporting documentation required is on the IRAS website at: https://www.myresearchproject.org.uk/.

Any researchers wanting to conduct research at SLH are expected to be able to provide evidence that any required approvals specified by the HRA or university ethics committees are in place. Review of this evidence will take place by the R&IO in accordance with this policy so that assurance of evidence can be provided to the CARG and CRDC via updates.

Documents required by St Luke's to facilitate Capacity & Capability

Research Study Protocol

The researcher or research team is expected to submit a protocol. A protocol is a set of instructions that describes in clear detail how the research will be conducted. As a minimum, a protocol includes a justification for the research, a research question, a detailed method for how the research will take place, a plan for analysis, and a plan for storage and eventual archiving or destruction of data.

There is no stipulated form for the protocol, as it is dependent on the nature and type of the project. The protocol may be taken from other documentation, such as an IRAS application, provided it contains the necessary detail as outlined above. The R&IO can provide a protocol template if required.

Study Amendments

An amendment is any change to the original study application during the life of the study. This includes but is not limited to: protocol amendments, updated study documentation, duration of the study, changes in study management (including sponsorship or funding) or changes to the leads of the research team (CI/PI). Amendments can be classified as Substantial or Non-Substantial, depending on whether they require approval either by the Research Ethics Committee (REC) and/or Medicines and Healthcare products Regulatory Agency (MHRA). Amendments can be classified as requiring study-wide review (notifiable) or not requiring study-wide review (non-notifiable) depending on whether they require approval from the HRA.

Substantial Amendment

A substantial amendment is a change to the terms of the REC application, the protocol or any other document submitted with the application, which significantly affects one or more of the following: • The safety or physical or mental integrity of study participants • The conduct or management of the study • The scientific value of the study • The quality or safety of any investigational medicinal product used in the study

Non-Substantial Amendments

Other changes to the study protocol or any other document submitted with the application to REC/HRA not meeting the above criteria are non-substantial amendments.

The R&IO must be made aware of all study amendments and be provided with all documentation relating to the amendment including new versions of the Patient/Participant Information Sheet & Consent form. These documents will be reviewed by the R&IO, recorded in the research register and presented to CARG for approval prior to their implementation in the hospice. Once approved the R&IO will send Amendment approval email (See Appendix 9) to the researcher.

Assessing Study Risk

Potential research may be considered to be low, medium or high risk. The assessed risk level determines the degree to which additional approval is required at SLH. Low risk studies are those which do not require additional approval. High risk studies will be referred to the CARG. Medium risk studies are expected to be the majority of cases and will be assessed at CARG. **Surveys or information to complete national evaluations which do not otherwise raise medium or high-risk concerns are considered as low risk and will presented to CARG for information purposes and be pragmatically managed by the R&IO. Details of the different risk levels with examples and implications for approvals are covered in Appendix 4.**

Research Register

The R&IO will maintain documentation which records all research conducted at SLH, from the time of first approach to the time a study closes and data is archived and eventually destroyed.

The Research Registers are electronic documents generated via Microsoft List software to track all research activity, and is used as a tracking tool for all research governance processes and its associated activity and updated in real time.

The registers are a database for storing all information about all research activity at SLH and relevant processes required for effective research governance. The database allows our research team to track our research progress in accordance HRA policy framework and our organisational strategic objectives. The database integrates with our internal reporting tools to generate easy to understand and visual overviews of our research progress based on our key performance indicators (KPI's).

The registers include progress of governance approvals, recruitment numbers, studies that are under consideration/in set-up/active/closed/archived, location of additional documentation, outputs, funding, CV & GCP compliance, academic activity, grants & studies in design, etc.

The SLH Company Drive has a shared folder for storing research-related information. This folder is accessible to specific members of the CARG and is maintained by the R&IO. Electronic records for each study are stored in this folder, according to the SLH study number and study title in the Research Register.

When a study has a site file maintained at SLH (mandatory for studies that recruit patients/participants), this will be kept in either secure files on-site in the R&IO or electronically on the SLH company drive.

Where a study does not have a SLH site file, the relevant documentation will be kept in the secure electronic files maintained by the R&IO. These folders record the SLH decision process and any research essential documentation.

For all studies conducted at SLH, the following information documented in *Table 1 – Research Governance Process & Evidence Map* is required and will be entered directly into the Research Register to assess the study from SLH's perspective. In most cases, these processes can be assessed and evidenced via the existing applications (whether HRA/REC or University-led) with additional detail requested as needed depending of Risk level by the R&IO.

NOTE: Not all are required depending on risk assessment

Table 1- Research Governance Process & Evidence Map

Item
Evidence to confirm all members of the research team have appropriate research training? Good Clinical Practice/Master's level University training are examples
Evidence to confirm relevant members of the research team have letters of access/substantive/honorary contracts and appropriate DBS clearance
Evidence to confirm the research proposal includes an appropriate risk assessment for the researcher
Evidence to confirm the research proposal includes an appropriate risk assessment for the participants and is entered into the research register
Evidence to confirm the research proposal includes an appropriate timeline and the start & stop dates are entered into the research register
Evidence to confirm the research proposal includes appropriate data protection and data management processes for the duration of the study, which account for the GDPR regulations and SLH DPO approval has been obtained and recorded in research register. (Liaise with SLH's Data Protection Officer)
Evidence to confirm the research proposal includes appropriate insurance. (Liaise with SLH insurers)
Evidence to confirm indemnity and sponsorship requirements
Evidence to confirm the research proposal includes appropriate plans for data storage, archiving and destruction following study completion and recorded in the research register
Evidence to confirm financial arrangements to perform the study including SoCAT, Grant funding if applicable, etc
Evidence to confirm impact and access to other staff groups/services etc has received line manager(s) approval of the staff involved
Evidence to confirm PPIE involvement (where appropriate)
Evidence to confirm Equality Impact assessment - Restrictive Practice Policy and Procedures V1 AUG2024.pdf
Evidence to confirm the research proposal includes appropriate consent processes. (Evidence should include the ethical approved consent form).

Evidence to confirm the research proposal includes appropriate patient/participant information (Evidence should include the ethically approved patient/participant information sheet).

NOTE- Evidence of the above will not be required for some low - risk studies and will be managed at the discretion of the R&IO and the R&IM.

Research Projects and Clinical Trials Initiated Elsewhere

If a patient under the care of SLH is involved in a research project initiated from another organisation, SLH will collaborate with the continuation of any therapeutic intervention, report adverse events, and provide feedback as requested i.e. – continue with prescribed medication, complete evaluation forms or write written reports as appropriate.

SLH will need to be informed by the patient or their next of kin of any such research project or clinical trial, and be provided with relevant information relating to the project, including contact details of the project organiser.

External Researchers at SLH

Those wishing to be involved in research at SLH who are not our employees or volunteers should make initial contact with the R&IO prior to initiating any research activity. They will require a contract with a university, NHS trust or similar organisation which acts as the main employer, supervisor or sponsor of the research.

An external researcher will need DBS clearance if they wish to work on SLH's site without a staff escort to access SLH's service users or their data. In addition, an external researcher will require a letter of access (see Appendix 7) or honorary contract if they wish to have on-site access to service users or their data, or attend the site unsupervised. This is arranged by the R&IO in conjunction with the Human Resources department.

External researchers who require an honorary contract or letter of access are required to attend an SLH orientation day to ensure they are well-appraised of the values and structures of the organisation. They will have a named manager who will conduct initial reviews in the first year and annual reviews thereafter; this may be the HoR/R&IM or another member of staff who has agreed to undertake this role.

If the researchers are not involving service users in any way, and will be escorted by SLH staff at all times, they may be able to conduct their research as a visitor; this will only usually apply to small-scale studies of staff. Advice should always be sought from the R&IO.

Access and Publication

Information on research being conducted should be accessible to staff and the public. This information should be available for all projects that have been given hospice approval and requests for information will be managed by the R&IO. This information will be updated on the hospice research website.

Study participants are frequently given the option to receive the results of research from the research team. In addition to this, publications related to research conducted at SLH will be displayed on the research section of the SLH website.

Wherever possible, the research findings should be published in relevant publications or peer review journals. All papers submitted should be approved by the person who is overseeing the research project. In addition, results should be shared with SLH's governance groups.

Implementation and Training

All individuals undertaking clinical research must have knowledge and training to ensure that the rights and safety of participants in research are protected. A key requirement for anyone involved in the conduct of clinical research is Good Clinical Practice (GCP) training. GCP is the standard and guidelines to which all research must be conducted. Training for this is available locally or via e-learning modules. GCP training should be completed every three years.

Additional training may be required to ensure that researchers are skilled in obtaining informed consent for any research being undertaken, and to ensure that they are able to undertake the specific requirements of the research protocols.

All members of staff involved must be competent and familiar with their roles and responsibilities in relation to the project in question. Contact the R&IO for further information relating to research courses and training including Good Clinical Practice (GCP).

Policy Monitoring and Review

There will be an annual report to the Board of Trustees on research activities when they occur, and an annual report to Healthcare Governance Group. These reports will provide assurance of adherence to this policy.

This policy and its associated procedures will be reviewed three-yearly, or when legislation or Department of Health guidance requires it.

Managing Approaches to Conduct Research

An approach to conduct research may be received from any number of sources, including face-to-face meetings, emails, conferences, or by post. The person receiving the request should inform the R&IO in the first instance.

The R&IO will review the request and liaise with the person or organisation making the request to determine whether SLH has the ability to uptake or be involved in the research. A decision not to be involved in the research will be discussed with CARG/HoR/R&IM/R&IO as appropriate and the R&IO is responsible for responding to the requesting organisation this decision.

If the decision is taken to consider SLH participation in the research project, the R&IO will enter the details of the study into the Research Register and ensure all evidence to provide assurance in accordance with the governance processes described in Table 1- *Research Governance Process & Evidence Map* are obtained and documented in the Research Register.

If the research is identified to be low risk, the R&IO will ensure the necessary sections of the research register are complete and present the study at the next available CARG meeting for information purposes only. This process will ensure the methodological approach is acceptable and the SLH reputation is upheld and considered. The R&IO will then provide approval by email (See Appendix 8 - Email Template for Approval of low-Risk Studies). It is not necessary to complete the full SLH Research Management Approval Form (Appendix 5).

For all other research, the R&IO will complete the SLH Research Register and the Research Management Approval Form (Appendix 5) and seek additional information from the researchers where required, the R&IO will work with the researchers to determine what is required in terms of contracts, letters of access and/or DBS clearance and record in the Research Register.

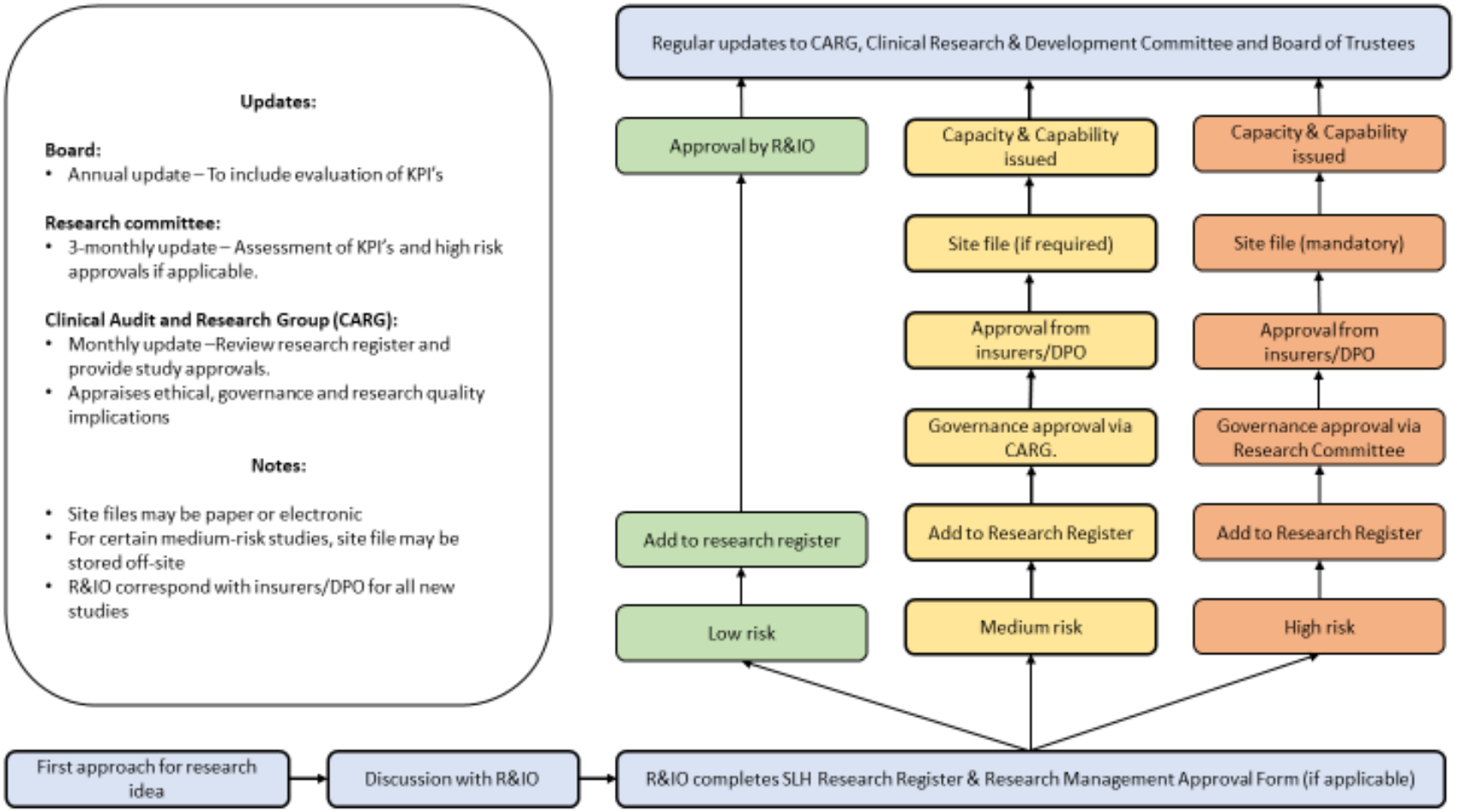
The R&IO will bring the information of the approach to conduct research to the next CARG; if the members of CARG require more information, the R&IO will liaise with the researchers to obtain this and report back to the CARG. Once the information is received and the SLH Research Register & Research Management Approval Form (Appendix 5) has been completed to the satisfaction of the CARG members, two members of the Group will sign their approval. *Where one of the CARG members is the lead researcher, they should not sign or counter-sign any approval pertaining to the study they are involved in.*

If the research is identified by the R&IO or CARG to be high risk, the R&IO will liaise with the Chair of the CRDC at the earliest opportunity to discuss approvals. This is

likely to involve delegating tasks to the CARG, but the research will require sign-off from a member of the CRDC.

After approval of the Research Management Approval Form (Appendix 5) the R&IO will generate a Research Capacity & Capability letter (Appendix 6) of approval for signing by the HoR/R&IM and/or executive members of the CARG. The R&IO will forward this to the researchers who are then permitted to undertake their research as stipulated in the study documentation. Updates will be provided to the CARG by the R&IO.

This process is summarised in the flowchart below and remains the responsibility of the Head of Research.


Updates:
Board:
• Annual update – To include evaluation of KPI's
Research committee:
• 3-monthly update – Assessment of KPI's and high risk approvals if applicable.
Clinical Audit and Research Group (CARG):
• Monthly update –Review research register and provide study approvals.
• Appraises ethical, governance and research quality implications
Notes:
• Site files may be paper or electronic
• For certain medium-risk studies, site file may be stored off-site
• R&IO correspond with insurers/DPO for all new studies
Regular updates to CARG, Clinical Research & Development Committee and Board of Trustees
Approval by R&IO
Capacity & Capability issued
Capacity & Capability issued
Site file (if required)
Site file (mandatory)
Approval from insurers/DPO
Approval from insurers/DPO
Governance approval via CARG.
Governance approval via Research Committee
Add to research register
Add to Research Register
Add to Research Register
Low risk
Medium risk
High risk
First approach for research idea
Discussion with R&IO
R&IO completes SLH Research Register & Research Management Approval Form (if applicable)

Managing Research Project Documentation Following Approval

Research projects cannot begin until the St Luke's Hospice Research Register; Research Management Approval Form; Capacity & Capability approval letter/Email and the Research Right of Access letter (If applicable) have been issued and sent to the Chief/Principal Investigator.

1. Any additional comments will be recorded in the comments section of the research register

2. If appropriate, the R&IO will include a copy of the indemnity certificate with the research documentation.

3. The R&IO will send a copy of the indemnity certificate and protocol to SLH's insurers for review and comment, and copy the Director of Finance & Chief Operating officer and the Projects & Compliance Manager into all correspondence.

4. Once the insurers have confirmed they are satisfied with the indemnity and protocol and have registered the project, the R&IO will record a copy of the confirmation for audit purposes in the research register.

5. A Research Capacity & Capability approval letter – see Appendix 3 - will be drafted by the R&IO and signed by 2 members of CARG. If HoR/R&IM/ Medical Director / Executive lead for Care/ Chief Executive & Chief Nurse / Chair of Clinical Research & Development Committee are involved in the research project, they will be precluded from the approval process.

6. All studies will be given an electronic site file where all approvals will be filed and if necessary, a paper version will be created for those studies where the researcher is not based at SLH or does not have one created by their own institution. For all studies, electronic records will be kept in the Company drive, as below.

7. Study information will be moved into appropriate folders as the research progresses, as below.

Research Register, Site Files and Electronic Files

Research Register

The R&IO will maintain an up-to-date Research Register of all studies on the SLH Company intranet. This register contains and tracks all research governance information in accordance with this document. The register includes but is not limited to:

Studies under consideration

- From first expression of interest to awaiting approval

Active studies

- Approval letter signed, collecting data

Ended studies

- Data collection complete, being analysed or stored pending further analysis

Closed studies

- Key publications generated and recorded; formal closure recorded.

Completed studies

- Data archived or destroyed

Non-research studies

- Reviewed and re-submitted as audit or service evaluation

Withdrawn studies

- Abandoned, discontinued or not funded

Researcher contact details

Protocol, patient/participant facing documents PIS/Consent etc./amendments with correct versions and dates.

Regulatory records including ethical approval, insurance, data protection and indemnity

Research and Development (R&D) records – refers to local approvals

Funding and sponsorship arrangements

Research personnel/CV & GCP compliance

Impact data including Publication/Posters/Conference presentations

Site Files (Electronic & Paper)

Research governance documentation for all research studies will be filed in the electronic site file in the SLH Company intranet Research File (S:\Research Shared)

It is the Principal Investigators responsibility to organise, manage, file and keep up to date the site file in accordance with the regulatory regulations and SLH R&IO will assist with this, if deemed necessary. The contents of a site file depend on the study type, but typically includes:

- Researcher contact details
- Ongoing correspondence
- Protocol and amendments
- Regulatory records
- Research and Development (R&D) records – refers to local approvals
- Funding and sponsorship arrangements
- Research personnel
- Participant documentation
- Screening and recruitment records
- Safety records and file notes
- Case Report Forms (used to record study findings)
- Monitoring
- Training
- Additional information

Additional information may be added to the site file depending upon the study itself.

SLH R&IO can provide a site file template if required.

A signed SLH Research Management Approval Form (Appendix 5) and a copy of the Research Capacity & Capability (Appendix 6) signed letter of approval will also be kept in the electronic site file in the SLH Company intranet Research File (S:\Research Shared) with the study documentation and accessible to members of the CARG.

References and Useful Links

Medical Research Council and NHS Health Research Authority decision tool available online at: http://www.hra-decisiontools.org.uk/research/ [Accessed 18/12/2024]

British Sociological Association (1994) Statement of Ethical Practice available online at: bsa_statement_of_ethical_practice.pdf

Department of Health Research Governance Framework for Health and Social Care (London, UK): Department of Health second edition 2005

National Research Ethics Service (NRES) http://www.nres.nhs.uk

Integrated research Applications System (IRAS) https://www.myresearchproject.org.uk

The HRA Medical Research Council Research Toolkit (a resource for independent hospices): Is my study research?

Appendices

Appendix 1: St Luke's Hospice Research Governance Framework

1. Operations, management and internal scrutiny

1.1 Day-to-day management of St Luke's research activity is undertaken by the R&IO under the direction of the Medical Director and Lead for Programme Development. As for any other departmental activity undertaken by St Luke's Hospice (SLH), the principal reporting and accountability line is to the Chief Executive and the Executive team as a wider group.

1.2 Research activity also requires significant collaboration and joint working with other departments and individuals. To aid this, St Luke's has a formed a Clinical Audit and Research Group (CARG), which brings together a wider membership from across the organisation. The Terms of Reference of the CARG is received, reviewed and approved by the Executive – and should be reviewed and approved at least every 3 years. Minutes of the CARG are made available to the Executive team.

1.3 Whilst day-to-day activities are run through the internal operational and management arrangements noted above, there is need for more formal governance oversight and approval reflecting SLH's governance structure.

1.4 All Standard Operating Procedures relating to the Research Governance Framework and the management of research at SLH will be available and stored on the SLH Research intranet & website.

2. Governance and approvals

2.1 The Board of Trustees is responsible for SLH's research strategy and for monitoring its delivery. The Board delegates this responsibility to the Clinical Research & Development Committee (CRDC), maintaining scrutiny and oversight through periodic reports and formal minutes, received and if necessary discussed and approved at Board meetings.

2.2 The CRDC operates under Terms of Reference (Appendix 3) approved by the Board, which are reviewed from time to time. These Terms of Reference specify the purpose and authority of the Committee and the information it is to receive; the Medical Director and Lead for Programme Development is responsible for servicing the Committee.

Amongst a wide range of duties, the CRDC is the formal body empowered to monitor and approve the most significant aspects of research activity. These include:

a) The research strategy
b) The research policy and procedures
c) Approval for significant projects and programmes i.e High risk studies
d) Approval for any project where the risk analysis exceeds a specified corporate tolerance level agreed by SLH's Audit and Risk Committee – including but not limited to risk to reputation, liability, ethics and data.
e) Approval for any project where the financial model exceeds specified parameters agreed with the SLH Director of Finance and Chief Operating Officer i.e. £10,000
f) Serious incidents, disputes, investigations or breaches of duty (including data)
g) Exceptional issues involving regulatory bodies, key relationships, or insurance issues
h) Evidence of insurance cover for the organisation, and for specific projects as necessary
i) Any other matters specifically requested by the Committee

The Committee will expect that all such matters referred to it will have been advised to, and considered by, the Chief Executive in advance of the Committee receiving the item.

In some circumstances it will be appropriate for the Chair of the Committee to act between meetings of the Committee; this is covered under the Terms of Reference.

The Research Committee will determine and approve the definitions to be used under items (c) to (e) above, which might change from time-to-time.

Items covered by (a) to (i) above which have not received approval through the Committee mechanism are not approved to proceed, until such approval is given.

APPROVED BY THE RESEARCH COMMITTEE

Appendix 2: Clinical Audit and Research Group (CARG) - Terms of Reference

1. Introduction

1.1 The Clinical Audit and Research Group (CARG) has been established to ensure all projects (research, audit, service evaluation & quality improvement) operate within an appropriate governance framework and that St Luke's Hospice (SLH) is not exposed to unmitigated or uninsured risk.

1.2 It is important that projects are relevant and add value to the organisation in terms of maintaining high standards, improving existing services and identifying service development opportunities.

1.3 The group will support the delivery of high-quality evidence-based care that supports organisational objectives for quality improvements.

2. Accountability

2.1 The CARG is accountable to the SLH Clinical Research & Development Committee (CRDC), and ultimately to the Board of Trustees.

3. Role and Function

3.1 On behalf of the above groups and committee the CARG will:

- Provide a clear framework for research, audit, service evaluation and quality improvement through which SLH will ensure the delivery of excellence in care through a programme of monitoring and evaluation;
- Receive, consider and approve or reject formal proposals for research, audits, service evaluations and quality improvement proposals based on local and national priorities including National Institute for Health and Care Excellence (NICE) Guidance, National plans e.g. National Clinical Audit & Patient Outcomes Programme (NCAPOP) and National Confidential Enquiries;
- Ensure all proposed studies meet required Department of Health and/or Health Research Authority research standards and have appropriate sponsorship, approvals, documentation and insurances including, where necessary, indemnity which extends to cover the hospice's non-negligent liability;
- Ensure work undertaken supports the delivery of Care Quality Commission standards;
- Ensure all proposed work is aligned to SLH's vision and values;

- Contributes to the annual quality account;
- Establish and monitor a rolling programme of audits and ensure repeat audits are undertaken in a timely manner;
- Ensure audit action plans as agreed by the Clinical Effectiveness Group are completed; and
- Provide regular activity reports to the Healthcare & Governance Committee and (audit, service evaluation) the CRDC (research, quality improvement).

4. Membership and Administration

4.1 The following roles form the core membership and attendees of the CARG; other people may be invited for specific topics or as part of developmental opportunities. (See Appendix 10 for a full list of current names)

- Chair - Head of Research/Consultant and Senior Clinical Lecturer
- Medical Director & Clinical Lead for Programme Development Executive Lead for Care
- Deputy Medical Director/Consultant in Palliative Medicine and Audit Lead.
- Research & Innovation Manager/Research Nurse.
- Head of Clinical Governance
- Head of Nursing
- Head of AHP's
- Clinical Quality and Risk Lead
- Nurse Consultant and/or Nurse/AHP with research interest (In attendance)
- Senior Research Fellow, School of Nursing & Midwifery, The University of Sheffield (In attendance)
- Executive Support/Research Administrator

4.2 For a meeting to be quorate at least three of the core members and one executive member must be present.

4.3 The Group will meet monthly, or more frequently if required.

4.4 Agenda, minutes, actions and papers will be circulated at least five working days before the meeting by the Executive Support/Research Administrator supported by the Risk Lead, Head of Clinical Governance, Clinical Quality & Risk Lead, R&IO & CARG.

5. Annual Review of the Group

5.1 The Group will undertake an annual self-assessment on their effectiveness and performance to:

- Review its own performance to ensure it is operating effectively;
- Determine whether its planned activities and responsibilities for the previous year have been sufficiently discharged; and
- Recommend any changes and/or actions it considers necessary, in respect of the above.

5.2 The Terms of Reference will be reviewed annually.

Appendix 3: Clinical Research & Development Committee Terms of Reference

Purpose of paper:	
For information	
For discussion & debate	
Requires decision or approval	

These Terms of Reference were approved by the Research Committee on 30 May 2024 and approved by the Board on 24 June 2024. The business section was added on post meetings.

This summary of the redrafted Terms of Reference was discussed with the other Chairs of committees who approved it. Once the Research Committee approves it, it will be worked up to include a list of business that is governed by the committee.

Proposed name change to Clinical Research & Development Committee

1. Purpose

The Clinical Research & Development Committee (CRDC) has the following principal roles:

- To be responsible to the Board of Trustees for the oversight, development, review, impact, funding and management of the portfolio of clinical research performed at St Luke's or by staff working for or on behalf of the organisation
- Shape the strategic direction of clinical research for the Charity based on research advances, local research expertise and areas of need
- To oversee St Luke's innovation and clinical development agenda *(including International Activity work)*, siting other relevant Committees
- To be principal stakeholder of the Wilkes Institute, responsible for three areas: research, education (with an internal focus) and development (with an external focus)

2. Governance and powers

Cross over with other Committees

The following aspects of the Committee's business will crossover to the following Committees:

Business	**Crossover/sight-of**
Elements of risks within studies	Audit & Risk Committee
International activity	Healthcare Governance Committee
Annual report of activity	Healthcare Governance Committee

Matters affecting staff members' remuneration or roles	Resource & Finance Committee

3. Membership and attendance

Membership of the Research Committee shall initially be as follows:

Chair and Trustees ('voting members')

- Chair:
- Trustees:
- Ex-officio: (Chair of the Board of Trustees)

Executive and staff

- Lead: (Medical Director and Lead for Clinical Programme Development)
- Exec members: (Director of Care Services); (Director of Finance and Chief Operating Officer); (Chief Nurse & Chief Executive)
- Staff members: (Consultant and Senior Clinical Lecturer); (Research Manager); (Head of Clinical Governance)

Lay members: (Specialist Palliative Care Chaplain); (Head of Research for Department of Nursing & Midwifery)

4. Chair, quoracy and conflicts of interest

At least two voting members (defined in section 3 above) must be in attendance for the meeting to be quorate. For the Committee to make decisions about resource allocation in addition to being quorate one of the following must be present: Chief Executive, Director of Finance.

5. Frequency of meetings

The Committee will meet at least four times per annum.

6. Administration and expenses

There will be a 4As report – the content of which is decided at the meeting - that will be discussed at the Board meeting to inform on the Committee's activities.

There is currently a designated fund that the Clinical Research & Development Committee has access to which is designed to help fund projects and the

development of the Committee's work. This will be managed through the Executive Lead.

7. Glossary

Clinical – used in St Luke's to include all medical, nursing, allied health professional, social work and spiritual care of patients and families

Development - internal and external Professional Development and innovation within St Luke's

8. Business

To oversee all aspects of SLH's clinical research and development by:

Clinical Research

- Owning and regularly reviewing the Research strategy to ensure it's fit for purpose and remains within the charity's aims and objectives
- Ensuring that all research is conducted to the highest ethical and clinical standards, complies with all relevant regulations and guidelines, and is conducted in an environment which supports the highest standards of research governance
- Reviewing progress made on research programmes and projects, receiving final reports, and considering future potential projects through horizon scanning
- Establishing and periodically reviewing measures of success and clinical impact of projects within the St Luke's research portfolio
- Regularly reviewing the research-active workforce
- Reviewing annual and other progress reports received from the Clinical Audit & Research Group (CARG)
- To consider any risks and alert Audit & Risk Committee
- Work with other committees to ensure that Clinical Research continues to have a high profile in the governance structure
- To invite external speakers to share insights for local, regional and national specialist Palliative Care research

Development

- To oversee the clinical innovation and development programme, including ECHO, and discuss outcomes
- To agree and oversee the scope of international activity, alongside other committees
- To be principal stakeholder of the Wilkes Institute, responsible for three areas:
    - Research
    - education (with an internal focus)
    - development (with an external focus)

- Oversee the impact and outcomes of the various visiting clinicians we have at St Luke's, including understanding the level of funding created

- Undertaking other matters in support of its objectives and aims.

9. Review date

Approved by Committee – May 2024

- Approved by Board – June 2024
- Review – May 2025

Appendix 4: Research Risk Levels

Research at St Luke's Hospice (SLH) is an important aspect of the organisation's agenda and ambition, and maps to one of the three charitable objectives. Research entails varying levels of risk, and SLH has a number of processes in place to assess and mitigate risk. Potential research is assessed and approved in two settings; the Clinical Audit and Research Group (CARG), which is a working group with executive representation, and the Clinical Research & Development Committee (CRDC), which is a strategic group with board level representation. SLH also has an Audit and Risk Committee, which addresses matters of risk for the organisation as a whole.

The purpose of this framework is to identify those studies which need a detailed review by the CRDC and, those which can be approved by the CARG. It is intended to capture all potential research and related activity being undertaken at SLH, from small-scale projects such as literature reviews and anonymous surveys, to large multicentre studies of interventions. The framework forms part of the SLH research policy.

Within SLH, potential studies will present various levels of risk which are likely to be the dominant factor in deciding what level of approval is necessary within the organisation. For the purpose of this document, risk levels are divided into low, medium and high. In keeping with SLH's organisational approach to risk, the following domains were used to structure the subsequent framework:

1. Innovation/Quality
2. Regulatory
    a. Methodology
    b. Data protection
3. Financial
4. People
5. Reputation
6. Governance

Risk Level Descriptions:

NOTE- All activity regardless of risk will be managed by the R&IO and documented in the Research Register accordingly.

Low risk studies reflect work which is of interest to SLH and poses minor risks in all domains described below but requires no mitigation outside of the project itself. Examples of low-risk studies include staff conducting literature reviews as part of an academic qualification, brief anonymous surveys or those requesting information to support national evaluations. These represent a significant proportion of the studies we are invited to support and the risk of such studies is minimal. These types of

studies considered as low risk by the R&IO will be presented to CARG and if the risk level is confirmed as 'low' will require no further governance and approval will be issued by the R&IM. *However, if the survey or questionnaire relates to sensitive subjects like assisted dying or specifically references St Luke's Hospice then the risk would not be considered low but medium or high and should be reviewed fully by CARG.*

Medium risk studies will be reviewed by the CARG, which has the ability to escalate to the CRDC if required. Medium risk studies pose risks to one or more domains which require monitoring by the organisation's governance structure. Examples of medium risk studies might be qualitative/quantitative studies (+/- as part of an academic qualification), surveys or questionnaire relating to sensitive subjects or that specifically reference SLH, involve consenting of patients and staff, identifiable or pseudonymised, etc.

High risk studies are those which require detailed assessment by the CRDC which has board representation. High risk studies are those which pose significant risk in one or more domains and require close monitoring and actions taken by the organisation to reduce impact. Invitations to take part in such studies are rare; since 2017, St Luke's has supported three such studies (StOIC, ACCESSA, & Chelsea II). Examples of high-risk studies are those that have the potential to alter a patient's treatment, include an intervention (+/- randomised), require informed consent of patients or staff including drug trials.

Please refer to the Health Research Authority (2023) UK policy framework for health and social care research. [Available from : UK Policy Framework for Health and Social Care Research - Health Research Authority] when assessing risk.

Principles for the risk assessment:

- The overall risk level of a study is the highest level recorded in any single domain. If, for example a study is low risk in most areas but high in others, it would be considered high risk.
- The final risk assessment level is recorded on the research register.
- Any study that scores medium in at least one category must be assessed at the CARG.
- Any study that scores high in at least one category must be assessed at the CRDC.
- Any one member of CARG, the CRDC, the Executive, the DPO and/or St Luke's insurers can request escalation to the CRDC for consideration, even where the apparent assessment of risk is medium or low.

Research Risk-Domain Descriptions:

The following is a framework including detailed descriptions of the risk domains and mapping study process and types to risk levels within these domains.

1) Innovation and quality

This risk framework is part of the wider SLH research strategy, policy and governance processes, which ultimately drive further development of innovation and quality assessments as part of the core aims of SLH. This framework can therefore be understood to come under the remit of innovation and quality as a whole. For the specific domains outlined below, we have proposed specific levels of risk and descriptors.

2) Regulatory risk.

Regulatory risk addresses issues related to the methodology and conduct of the study and the use of data. Methodological and conduct issues are typically addressed in detail by an external assessment conducted by the Health Research Authority (HRA), an NHS Research Ethics Committee (REC) a University Ethics Committee, and or another independent body. These aspects relate to ensuring that a study is safe for participants, ethical, and likely to yield scientifically rigorous results.

2a) Methodology and conduct:

Low:

It is proposed that the following study types are considered low risk:

- Studies that do not involve staff, premises, patients or service users as participants or subjects for study.
    - (For example, where staff are supporting research conducted elsewhere).
- Literature reviews undertaken by staff/students with the agreement of their managers.
- Staff surveys that are:
    - Anonymous, including to the researcher
    - Not able to identify St Luke's responses

Medium:

It is proposed that the following study types are considered medium risk. Multiple examples including:

  - Surveys of staff or service users where responses can be identified by the researchers.
  - Interview and focus group studies.
  - Epidemiological studies.
  - Studies of facilities, processes and premises.

High:

It is proposed that the following study types are considered high risk:

- Any study that involves the possibility of changing patient care. Examples include:
  - Randomised controlled trials
  - Studies of a proposed approach to symptom management
  - Studies of complementary therapies.
  - Studies which have the potential to alter a patient's treatment
  - Intervention studies and drug trials

2b) Data:

The main issues for data risk relate to a need to adhere to General Data Protection Regulations (GDPR) and use of identifiable data. For these reasons, the hospice Data Protection Officer (DPO) is routinely asked to give an opinion on studies involving data connected to individuals and will determine whether such studies are high risk.

It should be noted that data which can be traced back to an individual via a study (for example, if the study has generated a code number for the individual) is not truly anonymised, and is described as pseudonymised.

Low:

- The study does not involve data related to individuals (e.g. a documentary study of hospice policies)
- All study data is fully anonymised at the point of collection and cannot be linked again to the individual, even by the researchers (e.g. online anonymous survey).

Medium:

- Identifiable or pseudonymised information is collected and/or managed in accordance with GDPR regulations. (e.g. audit-style methods, or prognostic studies.)

High:

Where we are considering carrying out processing that utilises new technologies, or where there is a likelihood that such processing could result in a high risk to the rights and freedoms of data subjects, we always carry out a Data Protection Impact Assessment (DPIA).

Pursuant to Article 35(3) and Recitals 84, 89-96, we consider processing that is likely to result in a high risk to include:

- systematic and extensive evaluation of personal aspects relating to natural persons which is based on automated processing, including profiling, and on which decisions are based that produce legal effects concerning the natural person or similarly significantly affect the natural person(s);
- processing, on a large scale, special categories of data;
- processing, on a large scale, of personal data relating to criminal convictions and offences;
- systematic monitoring of a publicly accessible area on a large scale (i.e. CCTV);
- new processing activities not previously used and those involving the use of new technologies;
- processing considerable amounts of personal data at regional, national or supranational level, which could affect many data subjects.

The DPIA will take place **before** the new processing activities or proposed changes occur.

3) Financial:

Resource implications relate primarily to expenses incurred by SLH, but also to ensuring that funds and resources allocated to research work are used transparently and do not impede other duties of research staff. The figure quoted is guidance and can be revised by the CRDC in light of organisational pressures.

Low:

- No resource commitment, or resource risk limited to staff time as part of an academic course, survey or information to complete national evaluations.

Medium:

- Resource commitment (or equivalent in staff time) is higher than for low risk, but is estimated £10,000 or less.

  - Note this includes any study where resource flows into SLH as well as out.
  - Note that such studies are assessed in CARG, which is attended by SLH Director of Finance.

High:

- Any higher resource commitment in terms of absolute cost or equivalent in staff time.

4) People:

In this domain, "people" is taken to refer to staff and volunteers connected with SLH; impact on patients and carers will be considered as part of the methodological aspects.

One consideration of the impact of research on people is their time commitment, which is addressed in part under financial risk and further here. A further impact on staff is the potential for distress when discussing challenging subjects. These are also addressed in the governance sections but will be outlined below.

It is assumed that staff will have undertaken the relevant training before taking part in any research; either as a research participant or as research delivery.

Low:

- Any staff time commitment is entirely voluntary, has approval of line manager, is part of an academic qualification that doesn't involve SLH staff or patients, is a survey or is providing information to complete national evaluations, or in staffs own time.
- Staff will not be identified in research and any potential impact for staff distress is low.

Medium:

- Resource commitment (equivalent in staff time) is higher than for low risk, but is estimated £10,000 or less.
  - Note that Staff time must also be approved by manager.

- Staff will not be identified in research. Potential for staff distress is identified, but this is considered in the governance processes and appropriate support in place.

High:

- Any higher resource commitment in terms of equivalent in staff time.

- Staff will be identified in research.
- Significant potential for distress or potential for distress not considered by researchers.

5) Reputation:

Reputation risk refers to aspects of research which have the potential to impact negatively on SLH's reputation, within and beyond Sheffield. This is arguably the most subjective of the categories, so should be approached with transparency and an open mind. The presence of members of the executive at the CARG help to identify issues of reputational risk.

Low:

- SLH's services, staff or service users will not be identified in the research.

Medium:

- SLH's and/or our staff will be identified as having contributed to the research, either by acknowledgement or in-text.

High:

- The study addresses a contentious topic and SLH's will be identified as a contributor in any way.
    - Contentious topics include but are not limited to: Assisted dying, studies where the primary focus is on protected characteristics (e.g. inequalities in provision of palliative care to specific protected groups), criminal matters. If in doubt, seek advice.
- SLH's care provision will be described, identified, and compared with other units.

6) Research Governance.

Governance risk is addressed through two routes – the first is through the appropriate regulatory assessments, which determine that a study is legal, ethical and compliant with GDPR

In addition, studies are routinely registered with SLH's insurers, who undertake their own assessments. For the purpose of this framework, additional governance risk is mapped to the insurer's opinion.

Low:

- The study scores as low risk for all other categories.

Medium:

- The study scores higher than low in any other category, but is assessed by SLH insurers and no additional concerns are raised.

High:

- SLH insurers propose additional stipulations to the research.

Appendix 5: St Luke's Hospice Research Management Approval Form

Study name	
Study type	
Documents reviewed and version numbers	
Principal Investigator	
Sponsor	
Funder (if appropriate)	
SLH Risk Level	**Low / Medium / High**

N/A if not appropriate

Plain English summary of proposed research study, with details on role of SLH's. Describe methods, timescales and recruitment targets where necessary. Continue onto additional sheets if needed.

Plain English summary

Algorithm tool to support research approval decision making

Question	Who to assess	Notes
Is the proposed study research?	HoR/R&IO	If NO, then these processes don't apply. See decision tool link below. If YES, continue this checklist.
Does the study require HRA/REC approval?	R&IO	There is clear guidance from the HRA on this: see decision tool link below. If YES, submit HRA/REC approval documentation.
Does the study require University approval?	R&IO	If YES, submit the following: 1. University approved documentation

		2. Hospice review checklist
Does the study have or require approval from any other organisation?	R&IO	To be assessed on a study by study basis. Completed documentation to be attached.

Above decisions assessed by R&IO. Decisions reviewed at CARG and CRDC.

NOTE: Low risk studies may be approved directly by the R&IO and recorded on the Research Register. For medium and high-risk studies, conducted at SLH, *Table 1 Research Governance Process & Evidence Map* of this document will be used to identify the governance procedures required as per the risk identified for that particular study. **If the risk of the study in in doubt always refer to CARG.**

It is expected that any medium or high-risk research study being conducted at SLH will have received approval from one of these sources, and so has had an independent assessment of ethical issues. For any study involving interventions or sensitive data, this is likely to require HRA/REC approval. For small-scale qualitative studies of hospice patients, University approval is likely to be sufficient. Follow the HRA decision tool for guidance: http://www.hra-decisiontools.org.uk/ethics

Assessor details

Once all the above evidence has been provided and recorded in the Research Register on the SLH Company intranet Research File (S:\Research Shared), two members of the Clinical Audit and Research Group (CARG) should sign this form.

For high-risk research, the study should also be assessed by the Clinical Research & Development Committee (CRDC), and signed by the chair of that group or their delegated representative.

Next steps required following completion of this form can be found in the Research Policy.

Assessor 1 name:	Assessor 2 name:
Assessor 1 signature	Assessor 2 signature:
Date of assessment:	Date of assessment:
HIGH RISK STUDIES ONLY Assessed by Clinical Research & Development Committee (date): Signature of Clinical Research & Development Committee member: Print name: Date signed:	

Note. If a member of the CARG or CRDC is leading this research, they may not also sign this form or the authorisation letter.

Appendix 6: Research Capacity & Capability Approval Letter Template

Date

Researcher contact information

Dear Principal Investigator,

RE: Insert research study title and the following information if applicable

REC Number

NIHR portfolio number

SLH study number

Thank you for sending St Luke's Research & Innovation Office your research

Insert Documents approved including DPO/Indemnity & Insurance details and dates.

PIS – *Insert version & date*

Consent form – *Insert version & date*

Protocol – *Insert version & date*

REC Approval Reference – *Insert number and date approved*

Indemnity supplied by – *Insert details*

SLH Insurance provided – *Insert date*

SLH Data Protection Officer – *Insert date*

(This list is not exhaustive and may include other documents such as the approved GP letter, Investigator Brochure, Study invitation email, etc.)

proposal and associated documentation for the above-named study. Your study has progressed through our internal governance processes described in SLH Research Policy & Procedures V3 dated 21/01/2025 and the following documents have been approved.

Based on our review of the proposed protocol and approvals provided, this study has been assessed by the St Luke's Hospice Clinical Audit and Research Group, who have granted research approval and support the study to commence. .

This letter authorises that research can begin on the hospice site, in keeping with the terms outlined in the letter of access provided by St Luke's *(delete this paragraph if not applicable to internal staff).*

As you undertake the research, we would ask that you undertake the following responsibilities:

- Please inform us of any further changes or amendments to any of the submitted documents at the earliest opportunity and note these will require approval prior to being used to manage the study.
- Please inform the R&IO of any untoward or adverse events arising from the research at the earliest opportunity
- Please keep a copy of this letter with any existing approval letters.
- Please maintain a site file (electronic or paper)for the duration of the study

Yours Sincerely

(Insert Name)
Medical Director and Clinical Lead
for Programme Development

(insert Name)
Consultant in Palliative Medicine
and Research Lead

(insert Name)
Research & Innovation Manager
(Only 2 signatures required - delete as appropriate)

(If the medical director or HoR are leading the study, the letter would be signed by the Director of Care or Chief Executive)

Appendix 7: Research Right of Access Confirmation Letter Template

Private & Confidential

[Date]

[Researcher name]
[Researcher title],
[Address]
[Email]

Dear Name

Permission to undertake research (Right of Access)

RE: Insert research study title and the following information if applicable

REC Number

NIHR portfolio number

SLH study number

St Luke's Hospice confirms your right to conduct the above referenced research at this organisation on the terms and conditions set out below. This right of access commences on [date] and ends on [date] unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing by the St Luke's Clinical Audit and Research Group – Research Capacity & Capability Approval letter.

St Luke's Hospice is satisfied that such pre-engagement checks as we consider necessary have been carried out.

You are considered to be a visiting researcher for the purposes of the research project. You are not entitled to any form of payment or access to other benefits provided by the St Luke's to their employees or workers and this letter does not give rise to any other relationship between you and St Luke's.

While undertaking research through St Luke's, you will remain accountable to your place of employment as [role] at [employer name] but during the period of time when you are exercising the right of access you are required to follow the reasonable instructions of St Luke's and the Head of Research , or those instructions given on their behalf. These will be given for operational or other organisational

purposes. (Insert name) will be your nominated manager for the purposes of your research work at St Luke's.

Where any third-party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your research work, you are required to co-operate fully with any investigation by St Luke's in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You are required to co-operate with St Luke's in discharging its duties under the Health and Safety at Work etc. Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others. You must observe the same standards of care and propriety in dealing with patients, staff and visitors as is expected of any contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments, if you have not already done so, you must notify St Luke's prior to commencing your research role.

You are required to ensure that all information regarding patients or staff remains secure and ***strictly confidential*** at all times. Any information that you are provided with or which comes to your knowledge must not be disclosed to any third party, person or organisation whatsoever at any time without our express permission. Further, you must ensure that you understand and comply with the requirements of the relevant Codes of Practice and UK Data Protection Laws, including General Data Protection Regulations. Furthermore, you should be aware that, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

St Luke's may revoke this letter and terminate your right to participate in the research project at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we at our absolute discretion consider to amount to be disruptive and/or prejudicial to the interests and/or business of St Luke's.

Your employer, the [employer name] is responsible for your conduct during this research project and may in the circumstances described above undertake a formal investigation into the matter in line with their policies and procedures. You acknowledge that we may be required to provide information to [employer name] in this instance.

No organisation will indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 2018 or, more broadly,

the General Data Protection Regulations. Any breach of the Data Protection Act 2018 or the General Data Protection Regulations may result in legal action against you and/or your place of employment.

If your current role or involvement in research changes, or any of the information provided in your engagement checks changes, you must inform your employer and/or place of employment through their normal procedures. You must also inform your nominated manager at St Luke's.

Yours sincerely

Chief Operating Officer

I confirm my acceptance of the details set out in this letter

Note: You may commence your study once this letter has been signed and returned to St Luke's Hospice R&IO.

Full Name (Block capitals) …….

Signed ……..

Date .....

Appendix 8: Low Risk Research Email Confirmation Template

Private & Confidential

Dear Name

Permission to undertake low risk research

RE: Insert survey/request for information/etc. title

Insert SLH study number

Your survey/request for information, etc. (*delete as appropriate)* has been evaluated as low risk and discussed at St Luke's Hospice Clinical Audit & Research Group on (insert date) *and approv*al has been given for this information/survey (delete as appropriate) to be shared/completed (delete as appropriate) with you by (*insert name of contact*).

Should you require any further information please contact the Research & Innovation Manager on the information below.

Yours sincerely

R&IM details

Appendix 9: Amendment Approval Email Confirmation Template

Private & Confidential

Dear Name

RE: Insert research study title and the following information if applicable

REC Number

NIHR portfolio number

SLH study number

Amendment #? Dated (insert)

Amendment #? To the above-mentioned study has been reviewed and discussed at the St Luke's Hospice Clinical Audit & Research Group on *(insert date)* and approval has been given for this amendment and its associated documentation to be implemented.

Insert Documents approved and now in use:

PIS – (Insert Version & date)

Consent form – (Insert version & date)

(This list is not exhaustive and may include other documents such as the approved GP letter, Investigator Brochure, Study invitation email, etc.)

It is the Principal Researchers responsibility to ensure that all old versions previously used in the conduct of this study are removed from circulation and the site file is updated.

Should you require any further information please contact the Research & Innovation Office on the information below.

Yours sincerely

R&IO details

Appendix 10: Current Names of Members and Staff Performing Specific CARG/CRDC Roles.

Below is the list of names and roles and their specific roles and responsibilities listed in this document.

Accurate as of January 2025.

CARG Membership

Membership of the Clinical Research & Development Committee is as follows:

Executive and research staff:

Other roles

Appendix 11: Additional comments, requirements and updates sheet

Date	Comment	Update
26/11/21	At the time this policy was agreed, it was recognised that the risk framework would need to be updated and aligned with the organisational risk framework. This has been drafted and is due for approval in the February 2022 CRDC meeting.	Incorporated into current version of policy (v2)
23/02/23	Current version of policy created, incorporates risk changes as above.	
21/01/25	The fundamental aspects associated with the governance framework at St Luke's Hospice have not changed and are still underpinned by the regulatory framework detailed and referenced in The NHS Health Research Authority (HRA). What has changed is the growth in research activity, infrastructure and the introduction of a new research register which has enabled us to further expand and develop specific research policies and procedures.	Incorporated in V3 dated 21/01/2025