

# SOP 15: Research Studies Involving Sue Ryder

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All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the R&D website:

[Research at our hospitals \(gloshospitals.nhs.uk\)](http://gloshospitals.nhs.uk)

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

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## Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	09/04/2014
1.1	Temporary version reflecting new changes on 18 <sup>th</sup> June 2014	18/06/2014
2.0	Reviewed and Updated along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs	26/08/2016
3.0	Review of contracting processes	08/09/2017
4.0	Rebranding to GHNHSFT and updating of contact details	31/03/2018
5.0	Updated references and reference codes, updated information on the approval process	22/11/2023

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

### Related Documents:

SOPs
SOP 10 Hosting CTIMPs and other Clinical Studies
SOP 12 Trial management system using EDGE
SOP 13 Monitoring Research Studies
SOP 14 Study Income Distribution
SOP 28 Application to the trust for Sponsorship of a CTIMP

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## **1. Introduction, background and purpose**

This SOP has been produced to outline the approval process for research studies that recruit from or have involvement with Sue Ryder, Leckhampton Court, Cheltenham.

For studies involving other Sue Ryder hospice sites advice needs to be sought from the Sue Ryder Research Governance Group.

## **2. Who should use this SOP?**

This SOP should be used by:

- Gloucestershire Hospitals NHS Foundation Trust Research and Development Department (Trust R&D)
- The Chief & Principal Investigator
- The Principal Investigator's research team
- Sue Ryder Research Governance Group
- SR employed staff supervising student projects

## **3. When this SOP should be used?**

This document should be referred to and considered as soon as practically possible within the setup phases / approvals processes in relation to studies recruiting NHS patients treated under contract with Sue Ryder.

## **4. Categories of study**

This SOP is applicable to the following types of study differentiated by sponsor:

- a) Commercial sponsored studies
- b) Gloucestershire Hospitals NHS Foundation Trust sponsored studies
- c) Third party sponsored studies (non-commercial)
- d) Student projects sponsored by an academic institution (with supervisory / study design buy-in from a GHNHSFT-employed Consultant)

#### **4.1 Sponsorship of a study by Sue Ryder**

In the event of Sue Ryder sponsoring their own research study, it will be the responsibility of Sue Ryder to undertake all feasibility and administrative setup complying with their Research Governance Group related processes.

### **5. Contractual Relationships**

This SOP recognises that patients receiving care at Sue Ryder, Leckhampton Court, Cheltenham, are NHS patients being treated under contract with Sue Ryder (SR).

The need for, and type of contract required, should be discussed as early as possible in the feasibility phase of any discussions between R&D and SR. In most cases, the NIHR model Clinical Trial Agreements/Organisation Information Document (mCTA/OID) are recommended – mCTAs are available for both Commercial and Non-Commercial Studies. OIDs are only available for non-commercial studies. Examples of arrangement could include:

- For externally sponsored studies recruiting only from Sue Ryder, an NIHR mCTA between the Sponsor and SR should be used.
- For any study where there is a transfer of finance between SR and The Trust an additional non-commercial mCTA will be adapted to describe the arrangements between SR and the Trust.
- For externally sponsored studies where recruitment is occurring in both SR and the Trust mCTAs may be used. Individual mCTAs will be used for each site to describe the arrangement between the Sponsor and SR or Trust.
- Where the responsibilities/delegated duties for both recruiting sites is the same, a Tripartite agreement between the Sponsor, Trust and SR may be adapted.
- For studies sponsored by The Trust and recruiting in SR, a modified mCTA will be used in all cases, developed in discussion with SR

The need for, and type of agreement, will be decided on a study-by-study basis in discussion with SR and any relevant external sponsors.

Any agreement that describes a flow of finance between any parties must be included as an appendix that details the payment schedule and amounts for the duration of the study.

## **6. Recruitment Figures**

National Institute of Health Research (NIHR) studies recruiting at Leckhampton Court are attributed to the Hospice and entered onto EDGE.

## **7. Sue Ryder internal processes**

Sue Ryder operates a quarterly Research Governance Group at which research studies are usually considered at a stage when feasibility is assured and HRA paperwork is complete. It is recommended that a draft contract is submitted to this group with all related setup paperwork.

This SOP recognises that some studies will need to be expedited through Sue Ryder Research Governance approval process, for example, low risk studies which meet a specified criteria can be considered for fast-track approval. When Trust services are subcontracted to Sue Ryder, each support department must confirm capacity to undertake the study and agreement to any targets or costs before capacity and capability can be confirmed. Capacity and capability approved will need to be issued by both GHNHSFT and Sue Ryder Research Governance Group.