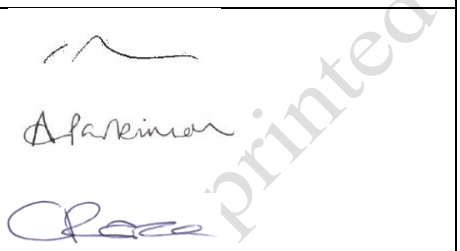
Gloucestershire Hospitals
NHS Foundation Trust

SOP 15: Research Studies Involving Sue Ryder

SOP reference:	SOP 15	
Version:	6.0	
Author:	Dr Paul Perkins Anne Parkinson Gemma Race	
Approved by Trust Senior Responsible Officer for R&I:	Claire Richardson 27/06/2024	
Implementation date of current version:		01/08/2024
Date of Review:		01/08/2027

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Innovation 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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&I website:

https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals

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.

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 18th 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
6.0	Name change of GHNHSFT R&D to R&I. Addition of glossary Addition of low-risk study process SOP validity updated to three years	01/08/2024

This SOP will be reviewed every three 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

Glossary

CI	Chief Investigator
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
mCTA	Model Clinical Trial Agreements
OID	Organisation Information Document
PI	Principal Investigator
R&I	Research & Innovation
SR	Sue Ryder

Contents

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 Innovation Department (Trust R&I)
- The Chief & Principal Investigator
- The Principal Investigator's research team
- Sue Ryder Research Governance Group
- Sue Ryder 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&I 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.

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 approval will need to be issued by both GHNHSFT R&I and Sue Ryder Research Governance Group. Confirmation of these approvals, and details of the feasibility/governance reviews if requested, will be provided to the other party prior to study commencing.

8. Low-risk Studies

Low-risk studies are classed as those solely recruiting/enrolling SR staff and involving research/evaluation methods of surveys/questionnaires/interviews or focus groups only.

These studies can be considered for fast-track approval through the Sue Ryder Research Governance approval process.

For these low-risk studies and where a GHNSFT subcontracted employee will act as PI, in place of a full Capacity and Capability review and approval, GHNHSFT R&I team will provide a simple approval email (Appendix 1.)

Prior to this approval being issued by GHNHSFT R&I, SR must provide all study documents that have been reviewed in the SR Governance process to the GHNHSFT R&I Department, including a copy of the SR Research Governance Group approval.

Appendix 1. Template Approval Email for Low-risk Study.

Subject: IRAS: xxxxxx - GHNHSFT Approval for Low-risk Study

Dear xxxx,

Study Full Title:

GHNHSFT Local Project Number:

Planned study Start date:

Planned end of study date:

This email confirms that GHNHSFT have received the information and all documents for the study mentioned above. This study is classified as low risk as it meets both the following criteria:

- Sue Ryder, Leckhampton, staff only, and
- Methods: Surveys, questionnaires, interviews, and focus groups

Sue Ryder's Research Governance Group have completed the necessary checks and issued their approval, a copy of which has been provided to GHNHSFT R&I.

We are happy for this study to commence and confirm support for xxxxxxx [*named Investigator]* to act as PI.

If you have any queries, please do not hesitate to contact me.

Best Wishes,

xxxxxxx