Gloucestershire Hospitals
NHS Foundation Trust

Management of Research 06: Research Studies Involving Sue Ryder

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 & 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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Reviewed by Associate Director of R&D	Julie Hapeshi / /	signature
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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

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

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 Development Department (Trust R&D)
- The Chief & Principal Investigator (contracted to Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) but based at Sue Ryder intending to conduct research involving Sue Ryder , Leckhampton Court, Cheltenham)
- The Principal Investigator's research team
- Sue Ryder Research Governance Group

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 pharmaceutical industry 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. In this circumstance, when sponsorship duties are fulfilled and the study submitted for review, it will be the responsibility of GHNHSFT R&D Department staff to

undertake research governance processes to issue NHS permission for the research to commence.

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 Care (SRC). This means that contractual relationships for research studies that involve patients at Sue Ryder can often be complicated.

Because of this 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 SRC. In most cases, the NIHR model Clinical Trial Agreements (mCTA) are recommended – mCTAs are available for both Commercial and Non-Commercial Studies. Examples of arrangement could include:

- For externally sponsored studies recruiting only from Sue Ryder, and NIHR mCTA between the Sponsor and SRC should be used.
- For any study where there is a transfer of finance between SRC and The Trust (in addition to any funding confirmed in the sponsor/host mCTA) and additional non-commercial mCTA will be adapted to describe the arrangements between SRC and the Trust.
- For externally sponsored studies where recruitment is occurring in both SRC and the Trust an mCTA may be used to describe the arrangement between the Sponsor and either other party (SRC or Trust) with an additional agreement in place with the third party to describe any further arrangements between sites. The decision on which party signs the main agreement will be based on the activity each site will be undertaking.
- Where the responsibilities/delegated duties for both recruiting sites is the same, a Tripartite agreement between the Sponsor, Trust and SRC may be adapted.
- For studies sponsored by The Trust and recruiting in SRC, a modified mCTA will be used in all cases, developed in discussion with SRC

The need for, and type of agreement, will be decided on a study by study basis in discussion with SRC 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

NIHR Portfolio adopted projects involving Sue Ryder that involve a Principal Investigator contracted to GHNHSFT will recruit patients with accruals attributed to GHNHSFT and entered onto EDGE.

7. Sue Ryder internal processes

Sue Ryder operates a monthly 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 meeting processes. For instance, if an urgent study (such as one adopted to the National Institute of Health Research Portfolio of priority research) emerged within a week of the last Sue Ryder Research Governance Group meeting taking place, and where the remainder of the month presented a delay on the approvals process, that such studies will be emailed to the Sue Ryder Research Governance Group for an approval in principle prior to being presented at the next Research Governance Group for information.

8. Other SOPs and documents

To be used in conjunction with this document, a number of SOPs are in place that relate to the setup / approval process for studies reviewed by GHNHSFT R&D Department including:

- R&D SOP RDVL 02 – Application to the trust for Sponsorship of a CTIMP
- R&SD SOP MR 01 Hosting CTIMPs and other Clinical studies
- R&D SOP MR 03 - Trial management system using EDGE
- R&D SOP MR 04 – Monitoring Research Studies
- R&D SOP MR 05 – Distribution of commercial income