Gloucestershire Hospitals
NHS Foundation Trust

SOP 17: Radiotherapy trial management at satellite sites

SOP reference:	SOP 17	
Version:	2.0	
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	22/09/2023	
Implementation date of current version:	30/10/2023	
Date of Review:	30/10/2025	

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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:

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

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	Not implemented
2.0	Formatting and grammatical corrections, Removal of SOP categories and change of reference codes	30/10/2023

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

Related Documents:

SOPs
SOP 04 - Informed Consent in Research
SOP 10 - Hosting CTIMPS and other clinical studies
SOP 11 - Confirmation of Capacity and Capability

Contents

1. Introduction, Background and Purpose

The purpose of this SOP is to set out the process for trial-related delivery when radiotherapy is delivered at Hereford County Hospital (HCH).

Hereford County Hospital is run by Wye Valley NHS Trust (WVNHST). The Radiotherapy Unit within the HCH is a satellite of the Gloucestershire Oncology Centre (GOC), Radiotherapy Department at Cheltenham. This HCH satellite unit was built by, and is run by Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT), who staff and manage the facility. Almost all patients will travel to Cheltenham for their initial planning session. Radiotherapy may be delivered across sites.

There are two pathways for patients receiving radiotherapy in Hereford to be offered trial participation.

Pathway A- clinical trials where the trial is open with support from the Gloucestershire Research Team only.

Pathway B- clinical trials where the trial is open with support from the Herefordshire Research Team. In this instance, the clinical trial is usually also open at GOC, although in some instances the trial may only be open in Hereford.

2. Who should use this SOP?

All staff working on a trial should be familiar with the procedures in place for patients receiving radiotherapy at Hereford County Hospital.

- Chief Investigator (CI) and trial co-ordinators of clinical trials sponsored or co-sponsored by the trust;
- Principal Investigator (PI) and research staff at sites where multi-site studies sponsored or co-sponsored by the Trust are being run;

- R&D office personnel, who manage the sponsorship of trials on behalf of the Trust and support Trust hosted trials;
- PIs and research staff for externally-sponsored trials “hosted” by the Trust.

3. When this SOP should be Used

This SOP must be referred to as soon as a trial is being considered for adding to the Trust trial portfolio. It should also be regularly referred to during the course of any trial delivery involving radiotherapy to ensure all staff are aware of the care/research pathways for these patients.

4. Radiotherapy Treatment Pathways

4.1 Pathway A- trial only open to recruitment and follow up at GHNHSFT Sites

- On the greenlight being given for a trial to open to recruitment patients may be approached about a trial within the radiotherapy department at HCH or within any other GHNHSFT site.
- Patients may consent to participate in a trial within the radiotherapy department at HCH or within any other GHNHSFT sites.
- The approach and the receipt of informed consent will be carried out by a staff member that has been delegated the responsibility by the Principal Investigator (PI) for the trial. This staff member will be an employee of the GHNHSFT. (Please refer to the SOP 04 - Informed Consent in Research).
- Radiotherapy may be delivered at either GOC or at the GHNHSFT radiotherapy satellite unit within WVNHST.
- Patients will be required to attend all cancer trial/radiotherapy related follow-up visits within the GHNHSFT sites. Follow-up activities include, but are not limited to clinician review and diagnostic

investigations. This requirement will be explained to the patient during the informed consent process.

- During the course of the radiotherapy, trial activity such as toxicity assessment and participant questionnaires may be conducted within the satellite radiotherapy unit at Hereford, over the phone, or in any of the GHNHSFT facilities.
- Following radiotherapy treatment, trial activities, including toxicity assessments and questionnaires may be conducted over the phone, by video conferencing or in a GHNHSFT facility.

4.2 Pathway B- trial open to recruitment and follow up at HCH.

- Where a trial is open to recruitment at HCH patients may be approached and may consent to participate in a trial at HCH.
- The approach and consent will be made by a staff member that has been delegated the responsibility by the Principal Investigator (PI) for the trial. This staff member will be a member HCH Research Delivery Team, GHNHSFT Therapeutic Research Radiographer or a Clinician at HCH.
- Radiotherapy may be delivered at either GOC or at the GHNHSFT radiotherapy satellite unit within WVNHST.
- All treatment follow-up and trial related activities will be conducted at HCH.

5. Trial Feasibility and Set –Up

As soon as a clinician or member of the radiotherapy delivery team becomes aware of a potential new trial involving radiotherapy contact should be made with

- the research delivery team at each site
- R&D teams at both GHNHSFT and WVNHST
- The Clinical Trials Unit to alert them to the arrangement and configuration of the GOC/ HCH Satellite Unit