Gloucestershire Hospitals
NHS Foundation Trust

SOP 32: Change of Principal Investigator

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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 adapt 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	01/08/2024

This SOP will be reviewed every three years unless changes to any relevant legislation requires otherwise

Related Documents:

SOPs
R&I SOP 02 - Research documentation and file management R&I SOP 10 – Hosting CTIMPs and Other Clinical Studies R&I SOP 12 - Trial Management System using EDGE R&I SOP 31 - PA Allocation Process

Glossary

GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
CI	Chief Investigator
ISF	Investigator Site File
PI	Principal Investigator
RO	Research Officer
R&I	Research & Innovation
TMF	Trial Master File

Contents

1. Introduction, Background and Purpose

The Principal Investigator (PI) is the health professional who takes responsibility for the conduct of the trial at their own site.

2. Who should use this SOP?

Principal Investigators for studies within GHNHSFT, any member of the R&I Professional Services Team and Delivery Teams, or any staff working on studies in the Trust, should use this SOP should there be a need for a change in PI.

3. When this SOP should be used

This SOP should be used if a PI is unable, or unwilling, to continue in their role as PI for a study, or studies within the Trust.

3.1 Unexpected absence

In the case of unexpected absence of the PI, e.g. prolonged sickness, that is under three months, the Sub-Investigator/s will be expected to deputise for the PI during their absence. If the absence extends beyond three months, this will necessitate a change of PI following the process below.

Study Sponsors should be kept fully informed of any PI absence by the delivery team, and all relevant correspondence copied to the R&I Professional Services team, filed in the ISF and uploaded to the relevant documents tab on EDGE.

4. Process for a change in PI

If a PI is unable, or unwilling, to continue as PI for a study they should inform the R&I Professional Services team in writing (ghn-tr.glos.rdsu@nhs.net), with a minimum notice period of eight weeks. Any notification regarding a change of PI

sent to the research delivery teams must be forwarded on the Professional Services team as soon as practically possible.

The PI should enquire with the study's Sub-Investigators, or other suitable colleagues, as to whether there is another individual willing to step into this role. The R&I Professional Services team, or research delivery teams, can provide assistance in establishing capacity and provide the necessary training or support for the proposed new PI.

If there are difficulties identifying a new PI, a Sub-Investigator on the study would be expected to take on this responsibility in the interim, this could be the R&I Specialist Research Doctor if appropriate to their skills and experience.

4.1 Process for a hosted study

The study Sponsor should be informed in writing of the proposed change in PI as soon as possible by the R&I Professional Services team (See Appendix 1, template sponsor notification email.). A signed and dated CV, and a valid GCP certificate for the new proposed PI should be shared with the Sponsor, and confirmation received that Sponsor accepts the new PI. If the PI at site was also acting as Chief Investigator for the study, a discussion should be had with the study Sponsor, as to whether proposed PI will take on the CI role as well.

The Sponsor will be responsible for submitting a study amendment to implement this change. This would usually only be a non-substantial amendment for a change of PI. At Trust, the R&I Professional Services, and delivery teams should follow guidance from sponsor to implement this change including update to any study documents, e.g. Patient Information Sheet (PIS), delegation log. All relevant delivery team members, and supporting depts, should be informed of this change.

Once the study amendment is approved at site, the study details should be updated on EDGE to reflect the change in PI, and details of the change recorded in the 'Notes' tab, by the RO's in R&I Professional Services team.

All relevant correspondence should be filed in the R&I folder, ISF and uploaded to the document tab on EDGE.

4.2 Process for a GHNHSFT sponsored study

A signed and dated CV and valid GCP certificate for the new proposed PI should be collected and filed by R&I Professional Services team. R&I Professional Services, as Sponsor representative, will be responsible for submitting the study amendment to implement this change. If the initial investigator was also acting as Chief Investigator for the study, this will require a substantial amendment. Updated documents, e.g. PIS, should be filed in R&I folder, TMF, ISF and uploaded to documents tab on EGDE.

All relevant team members, and supporting depts, should be informed of this change. Once the amendment has been approved, study details on EDGE should be updated by the RO's in R&I Professional Services, to reflect the change in PI / CI and details of the change recorded in the 'Notes' tab.

All relevant correspondence should be filed in the R&I folder, TMF and ISF.

Appendix 1 – Template sponsor notification email - change of PI for a hosted study

To: Sponsor

Cc: Current PI / New PI / Research Matron/s / Delivery Team Research Lead

Subject: [*Study Title] - Change of PI notification – GHNHSFT*

Dear [Sponsor reps/s]

Due to [*changes at site / upcoming retirement / staff changes – detail as needed*] *[current PI]* will be stepping down from the PI role for *[study name]* at GHNHSFT as of [*date*]. Their colleague [*proposed PI]* has agreed to step into this role. Please find attached a signed and dated CV and GCP certificate for [*proposed PI].*

Please let us know if you require other information or documents to facilitate this change at site. Please keep us informed of the progress of the study amendment to implement this change.

I would be grateful if you could acknowledge receipt of this email.

Many thanks

R&I Professional Services