NHS
Gloucestershire Hospitals
NHS Foundation Trust

Management of Research 04 – Monitoring Research Studies

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Author:	Janet Forkes	signature
Reviewed by Associate Director of R&D	Julie Hapeshi 27/ 03/ 2018	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 R&D SOP 05	
2.0	Reviewed and Updated along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs	08/08/2016
3.0	Rebranding to GHNHSFT, updating contact details and reference documents	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

To ensure that all sponsored and hosted research within Gloucestershire Hospitals NHS Foundation Trust (Trust) adheres to the expected standards of the Trust, this SOP describes the monitoring process that will be employed to review standards and assure compliance.

This SOP aims to describe a process that will cover the majority of projects through a self-completed Monitoring Tool where the Sponsor does not monitor either by visiting the research team or remotely monitoring. The Trust's R&D Department will monitor Trust Sponsored CTIMPS and hosted trials.

2. Who should use this SOP

All members of staff should be aware of this SOP, but it will be the responsibility of the R&D Managers to ensure that it is implemented.

3. When this SOP should be used?

This SOP will be used on an annual basis to monitor an agreed number of the Trust's research projects. The SOP applies to all Trust hosted and sponsored studies and, in relation to sponsored CTIMPs, will be used to ensure compliance with ICH/GCP, the UK Policy Framework for Health and Social Care Research, the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) and all other relevant legislation applying to the trial in question.

4. Monitoring Process

On an annual basis, a list of currently active projects and their investigators will be collated from the EDGE database.

The Self-Audit Monitoring Tool (SAMT) will be sent to all Chief Investigators of Sponsored studies and 10% of hosted studies on an annual basis in April.

4.1. Sponsored Research Studies (CTIMPs)

All CTIMPs sponsored by the Trust besides completing a SAMT will also be monitored by members of the GRSS on an annual basis to ensure compliance with all applicable regulatory guidance.

Upon receipt of a completed SAMT, the R&D team will record the response and note any issues that may require further investigation in the monitoring log. If the return does not raise any issues of concerns, no further action will be taken unless the study is chosen, at random, for detailed monitoring as per Section 4.2 and 4.3

The tool will be sent out with a suggested completion date. Failure to return by that date may trigger a detailed monitoring visit as per section 5.

4.2. Sponsored Research Studies (non-CTIMPs)

All Trust sponsored non-CTIMP research will be monitored in the same way as Trust Sponsored CTIMP studies

4.3. Hosted Research Studies (CTIMPs and Non-CTIMPs)

As a guide 10% of hosted research studies will receive the SAMT.

After the SMAT closing date, all non-responders and 10% of responders will be visited by a monitoring team from the GRSS team to ensure compliance with all applicable guidance and regulatory requirements.

5. Monitoring Visits

Monitoring visits will be arranged on a mutually convenient day and time with the CI/PI/ Research Team and the GRSS team. The monitoring visit will be performed by an R&D Manager and other members of the Trust R&D team dependent upon the size of the study or any pre-identified issues.

The Trust monitoring tools will be used on the monitoring visit to record the condition of the Site Trial Management File and the Patient Records.

The Trust R&D team will issue the Monitoring Report to the PI within 1 week of the visit. If there are any issues that need resolving, the report will specify timelines for addressing these issues usually within 6 weeks from the issue date of the report.

If there are no outstanding issues the report will consider the monitoring of that study closed until the following year.

6. Follow-on Monitoring Visit

Where a follow-on monitoring visit ie required it will be conducted as per section 5.

If there are still outstanding issues following the second monitoring visit a meeting will be arrange with the PI/ Research Team, the R&D Manager and Assistant Director of R&D to discuss plans to rectify outstanding concerns.

If these issues cannot be resolved at this point, the study may need to be suspended while the issues are addressed or closed to recruitment if there are potential risks to the patients/participants/staff or Trust.

7 Related SOPs and other Documents

R&D SOP TD 01 Research Documentation and File Management

R&D SOP PH03 Research Misconduct and Fraud

Appendix 1 SAMT –

Gloucestershire Hospitals NHS Foundation Trust
Research Governance Audit Tool

This tool is designed to help ensure your research is conducted within the UK Policy Framework for Health and Social Care Research. The criteria used in this tool are those set by the Framework and current best practice. All R&D projects conducted within or in conjunction with the Gloucestershire Health Community should be conducted within this framework.
Detailed guidance can be found in:

- UK Policy Framework for Health and Social Care Research v3.3 07/11/17
- Trust policies and Standard Operating Procedures (Available from your Research and Development Office and Intranet Site)

or contact Julie Hapeshi, Associate Director of R&D, Gloucestershire Research and Development Support Unit, for advice and guidance (Tel: 08454 225460, Email: Julie.Hapeshi@nhs.net)

SECTION 1

Project Title: .....
.....

Research Ethics Committee Ref: .....
R&D Reference Number: .....

Name of Lead Researcher: .....
Chief or Principal Investigator

(circle as appropriate)

Lead Researcher's Place of Work: .....
Name of Research Sponsor: .....
Research Funder: .....

Start Date of Project: ____ / ____ /_____ Planned End Date of Project : ____ / ____ /_____

Actual end date, if study complete: ____ / ____ /_____

Study status:
- ☐ **Pending** *(please go directly to section 7)*
- ☐ **Open to recruitment**
- ☐ **Closed to recruitment / in Follow-up** (finished recruiting subjects)
- ☐ **Abandoned** *(please explain why)*
- ☐ **Completed – report pending** *(please send a copy when available)*
- ☐ **Completed – report written** *(please send a copy with this form)*

Reasons for abandonment:

If closed or completed has appropriate effort been made (or planned) to disseminate the research findings, to the research participants AND other users/carers? ☐ **Yes** ☐ **No**

Has appropriate effort been made (or planned) to publish research findings, where appropriate in professional or peer reviewed journals?

☐ **Yes** (*please describe dissemination plan below)*
☐ **No** (*If no, please explain why)*

Comments:

If not published, is any other study report available? *Please attach a copy, summary or explain why a report is not available.* ☐ **Yes** ☐ **No**

If No, why not:

If closed, abandoned or completed, has the Research Ethics Committee (REC) been informed?

☐ **Yes** (*please attach copies of the letters to and from the Ethics Committee)*
☐ **No** (*If no, please explain why)*

SECTION 2

ETHICAL REQUIREMENTS:

(i) If the research protocol has been amended **in any way** since the favourable opinion was given, have the amendments been approved by the REC?

Yes ☐ **No** *(contact R&D team)* ☐ **Not Applicable** *(non substantial amendment)* ☐

(ii) If the research protocol has been amended **in any way** since the favourable opinion was given, have the amendments been approved by Trust R&D Office?

Yes ☐ **No** *(contact R&D team)* ☐ **No Amendments** ☐

(iii) Is there a list of all research participants (clients or healthy volunteers) within your site file?

Yes ☐ **No** ☐ **Not Applicable** ☐

(iv) Is there a full record of all research participants' written informed consent and/or where appropriate written carer assent?

Yes ☐ **No** ☐ **Not Applicable** ☐

(v) Where the study has been running for more than 12 months, have the appropriate Annual Reports been submitted to the REC that gave the original Favourable Ethical Opinion

Yes ☐ *(please submit copies to the R&D Office)* **No** ☐

If No, why not:

SECTION 3

GOVERNANCE:

(i) **Research Interactions with Patients:** Is there a record of research interactions with each patient in their notes (including off-site patient contacts)?

☐ **Yes**
☐ **No**
☐ **Not Known**
☐ **Not Applicable**

Comments

(ii) **Informed consent/patient information sheet:** Was the ethically approved version of the consent form used for each patient?

☐ **Yes**
☐ **No**
☐ **Not Known**
☐ **Not Applicable**

Comments

(iii) Is there a copy of the consent form in every patient's notes?

☐ **Yes**
☐ **No**
☐ **Not Known**
☐ **Not Applicable**

Comments

(iv) Does the ethical approval cover the version of consent form in use?

☐ **Yes**
☐ **No**
☐ **Not Known**
☐ **Not Applicable**

Comments

(v) Does the ethical approval cover the version of the information sheet in use?

☐ **Yes**
☐ **No**
☐ **Not Known**
☐ **Not Applicable**

Comments

(vi) If the research involves a novel treatment, intervention, clinical procedure, new equipment or new drug, have appropriate procedures for indemnity been arranged with the Trust?

Yes ☐ **No** ☐ **Not Applicable** ☐

(vii) Is all research data stored in line with the Data Protection Act requirements and Caldicott recommendations?

Yes ☐ **No** ☐

(viii) Do you have a site / management file available?

Yes ☐ **No** ☐

(ix) Is there a copy of the delegation / responsibility log within the site file?
Yes ☐ **No** ☐

(x) If your study is a clinical trial, please attach a copy of your completed delegation / responsibility log

Attached ☐ **Not Applicable** ☐

(xi) Do you have Annual Safety Reports available?

Yes ☐ **No** ☐ **Not Applicable** ☐

(x) If the study is a Clinical Trial of an Investigational Medicinal Product (CTIMP), under the Medicines for Human Use (Clinical Trials) Regulations, have the appropriate Development Safety Update Reports been submitted to the Medicines and Healthcare products Regulatory Agency (MHRA)?

Yes ☐ *(please submit copies to the R&D Office)* **No** ☐ **Not Applicable** ☐

If No, why not:

SECTION 4

HEALTH & SAFETY REQUIREMENTS:

(i) Have researchers involved in conducting the research (including non-Trust personnel) received Trust Health and Safety training/guidance?
Yes ☐ **No** ☐ **Not sure** ☐

(ii) Is there a record of all adverse events (clinical and non-clinical including any not specified in the protocol) arising during the research (or which you become aware of from other research)?
Yes ☐ **No** ☐ **Not Applicable** ☐

(iii) Have the Trust, the REC and the MHRA (where applicable) been notified of all adverse events?
Yes ☐ **No** ☐ **Not Applicable** ☐

(iv) Do all non NHS researchers who have contact with clients that "may have a direct bearing on the quality of their care" hold a Trust NHS honorary contract?
Yes ☐ **No** ☐ **Not Applicable** ☐ **Not sure** ☐

SECTION 5

FINANCE AND INTELLECTUAL PROPERTY RIGHTS (IPR) REQUIREMENTS:

(i) Has the Trust Finance Department approved all agreements/contracts made with external funders?
Yes ☐ **No** ☐ **Not Applicable** ☐ **Not sure** ☐

(ii) Have the Trust R&D Office given approval for all excess Treatment Costs and Service Support Costs incurred during the course of the research?

Yes ☐ **No** ☐ **Not Applicable** ☐ **Not sure** ☐

(iii) Are there agreements covering intellectual property rights (IPR) with any third party researchers/organisations/companies, and have these been approved by the Trust's R&D Office? This may include sharing of data/materials etc with any parties outside the Trust.

Yes ☐ **No** ☐ **Not Applicable** ☐ **Not sure** ☐

SECTION 6

GOOD CLINICAL PRACTICE:

(i) Have you and members of the research team received GCP training

Yes ☐ **No** ☐

If **Yes**, please list names, dates and providers below:

Name	***Date***	***Provider***
.....	.....	
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If **No**, please list names of those who require training *(we will contact you to arrange)*:

Name	***Date***	***Provider***
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

SECTION 7

Form completed by:

Name: .....

Job title: .....

Role in project: .....

Date completed: .....

Documentation attachments:

- *Study completed - copy of final report* ***Attached*** ☐ ***Not Applicable*** ☐
- *Completed but not published - copy of study report or summary* ***Attached*** ☐ ***Not Applicable*** ☐
- *Study closed, abandoned or completed – copies of letter to and from the Research Ethics Committee* ***Attached*** ☐ ***Not Applicable*** ☐
- *Copy of delegation / responsibility log* ***Attached*** ☐ ***Not Applicable*** ☐
- *Copies of Annual Reports submitted to the REC* ***Attached*** ☐ ***Not Applicable*** ☐
- *Copies of Development Safety Update Reports* ***Attached*** ☐ ***Not Applicable*** ☐

Please return this form and attachments to:
Sue Woods, Office Manager / Research Administrator, Gloucestershire Research Support Service, Leadon House, Gloucestershire Royal Hospital, Great Western Road, Gloucester GL1 3NN

Appendix 2 TMF/ ISF Checklist

Gloucestershire R&D Office - CTIMP Monitoring Checklist

TMF File/Investigator Files Content Review

Study Title: .....

Ethics Reference: .....

R&D Reference: .....

Chief Investigator: .....

Date of Monitoring Visit: ...../...../.....

Visit Type: First Visit/Follow-up* (*delete as appropriate) see below:

Date of first/previous visit: ...../...../.....

Title of Document	TMF/ Investigator Files	
	Copy Present? (Yes or No)	Comments
Before the Clinical Phase of the Trial begins		
Investigator Brochure		
Signed Protocol and amendments (if applicable)		
Sample CRF		
Information Sheet		
Consent Form		
Other patient documents (GP letter, contact letters etc)		
Advert (if applicable)		

Title of Document	TMF - Investigator Files	
	Copy Present? (Yes or No)	Comments
Before the Clinical Phase of the Trial begins		
Financial costings and agreements		
Insurance statements (if required)		
Signed Agreements between all Parties (e.g. mCTA)		
REC Favourable Opinion Letter (including composition of REC)		
MHRA Clinical Trial Authorisation		
Investigator/Research Team CVs		
Normal Values/Ranges for Labs (if required)		
Medical/laboratory/technical procedures/tests (as appropriate)		
Sample of Labels/product containers (if applicable)		
Instructions for handling IMP and trial related material (if not in protocol/IB)		
IMP Shipping Records (if applicable)		

During the clinical conduct of the Trial		
In addition to the above, the following documents (as applicable) should be added to the TMF as they become available and/or relevant.		
Investigator Brochure updates		
Revisions to Protocol, PIS, consent, GP letters, adverts etc.		
REC Amendments		
MHRA CTA Amendments (if applicable)		
CVs for new investigators/members of research team		
Updates to Normal Values/Ranges for Labs (if required)		

Title of Document	Copy Present? (Yes or No)	Comments
During the clinical conduct of the Trial		
Certificates of analysis of new batches of investigational products shipped (if applicable)		
Monitoring Visit Reports		
Relevant Communications (letters, meetings, reports, etc.)		
Signed informed consent forms		
Source Documents - *to document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject*		
Signed Dated and completed CRFs		
Documentation of CRF corrections		
SAE events and reports (including reporting to sponsor and from sponsor to REC/Competent Authority)		
Notification of safety information from Sponsor to Investigator		
Interim and annual reports to the IRB		
Annual reports to competent authority (MHRA) for CTIMPS		

Title of Document	TMF - Investigator Files	
	Copy Present? (Yes or No)	Comments
During the clinical conduct of the Trial		
Subject Screening Log		
Subject Identification code list		
Subject Enrolment Log		
Investigational Products accountability a the site - *to show IMPs have been used according to protocol*		
Signature Sheet, if not included on Delegation Log - *to record all those authorised to sign CRFs*		
Delegation log, including signatures of those authorised to sign CRFs		
Record of retained body tissue/fluids (if applicable)		

Title of Document	TMF - Investigator Files	
	Copy Present? (Yes or No)	Comments
After completion or Termination of the Trial		
Audit Certificate - *to show monitoring and audit has taken place*		
Final Trial close-out report - *to document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files.*		
Treatment allocation and decoding documentation - *to record any decoding that has taken place - should also be returned to Sponsor*		
Final report to Ethics		
Final Report to MHRA		
Clinical Study Report/Publications		

Appendix 3

Gloucestershire R&D Office - CTIMP Monitoring Checklist

Participant Medical Records Review

Study Title: .....

Ethics Reference: .....

R&D Reference: .....

Chief Investigator: .....

Date of Monitoring Visit: ...../...../.....

Visit Type: **First Visit/Follow-up*** **(*delete as appropriate) see below:**

Date of first/previous visit: ...../...../.....

Patient Identification Number:

Title of Document/Source Data(as applicable and not exhaustive)	Copy Present? (Yes or No)	Comments
Trial Alert Sticker		
Information Sheet		
Consent Form		
GP Letter		
Annotation confirming Consent and Recruitment to study		
Annotation regarding refusal to participate		
Annotation confirming Randomisation outcome		
Annotations regarding follow-ups		

Title of Document/Source Data(as applicable and not exhaustive)	Copy Present? (Yes or No)	Comments
Other documents please specify		
Other documents please specify		
Other documents please specify		
Other documents please specify		
Other documents please specify		
Other documents please specify		
Other documents please specify		
Other documents please specify		

Notes:

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Appendix 4 - Monitoring Report

Gloucestershire Hospitals NHS Foundation Trust

Monitoring Report

Study Title:	
Investigator:	
Sponsor:	
Ethics Reference:	
R&D Reference	
Date of visit:	
Type of visit:	
Monitor:	
Report completed by:	
Date of Report:	

1. **Trial Management File Review**

2. **Participant Notes Review**

   2.1. There are currently XX participants at various stages of the study. At the monitoring visit there were XX sets of notes available for review.

   2.2. Specific issues relating to each set of notes is included below. However, it is important to remember that issues may apply across all participants and repeated issues will need to be checked against the participants' notes that were not seen at the monitoring visit.

Participant Reference Number:		
Finding		**Action**
1		
2		
3		
4		
5		
6		

(replicate above table as required)

3. General Findings

4. Summary