Gloucestershire Hospitals
NHS Foundation Trust

SOP 21: Research Misconduct and Fraud

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Approved by Trust Senior Responsible Officer for R&I:	Noel Peter 29/05/2025	
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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 & 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:

Standard Operating Procedures (SOPs)

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	30/01/2015
2.0	Rebranding to GHHNSFT and updating contact details	31/03/2018
2.1	Inclusion of flow chart	31/05/2018
3.0	Updating design of SOP. Renewal period set at three years Removal of appendices, link with Trust policies.	03/07/2025

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

Related Documents:

GHNHSFT Policies:
B0132 – Counter Fraud, Bribery and Corruption B0312 – Freedom to Speak Up: Raising Concerns

Glossary

GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
HR	Human Resources
PS	Professional Services
R&I	Research & Innovation
UKRIO	UK Research Integrity Office

Contents

1. Introduction, Background and Purpose

Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) expects all research involving their patients, staff and resources to be conducted according to the highest standards of research practice and in accordance with GCP guidelines, the UK Policy Framework for Health and Social Care Research and applicable regulations. This applies whether GHNHSFT is acting as the host or the sponsor of the research.

While it is expected that an allegation of research misconduct or fraud will be a very rare occurrence, research misconduct or fraud is unacceptable and this SOP outlines the procedures for reporting, investigating and responding to such allegations against staff undertaking research studies in the Trust. This is to ensure that the process is fair and protects all the parties concerned.

The UK Research Integrity Office (UKRIO) describes research misconduct as "'behaviours that deliberately or recklessly fall short of the standard expected in the conduct of research', from the initial idea through to reporting outcomes." Examples of research misconduct may include, but not limited to:

- Plagiarism
- Breaching legal, ethical and professional requirements
- Fabrication
- Falsification
- Misrepresentation of data or other information
- Failing to declare or appropriately manage conflicts of interest

Research misconduct or fraud can also include acts of omission, as well as acts of commission. Research misconduct does not include genuine errors or differences in approach and methodology.

2. Who should use this SOP

This SOP should be used by anyone wishing to make an allegation of research misconduct or fraud against a member of staff in the Trust and by staff who are responsible for investigating such allegations.

All GHNHSFT staff have a duty to report any incident of misconduct, whether witnessed or suspected.

3. When this SOP should be used

This SOP should be referred to when an allegation of research misconduct or fraud is suspected or has been made. It should not be used to investigate other forms of misconduct.

This SOP should be used in conjunction with any existing relevant procedures within the Trust.

4. Procedure(s)

4.1 Identification / Reporting of Suspected Research Misconduct or Fraud

Any staff member within GHNHSFT or a member of the public may report suspected research misconduct or fraud. Concerns can also be raised through the GHNHSFT Freedom to Speak Up Service (as per Trust policy B0312: Freedom to Speak: Raising Concerns (Whistleblowing)). It is also possible that concerns about research misconduct or fraud may be identified during routine monitoring, audits or regulatory inspections.

Allegations or concerns should be made in writing to a senior member of the R&I Department, that is the Director of R&I, R&I Business Manager or R&I Professional Services (PS) Manager.

Named individuals (the respondent/s) will be made aware of allegations made against them, and the evidence received. The timing of this disclosure will depend on the nature of the allegation.

4.2 Investigation of Suspected Research Misconduct or Fraud

The Director of R&I or appropriate delegee, unless a conflict of interest is identified, will lead the investigation process and, in due course, take decisions

based on the outcome of the investigation. The Director of R&I will not conduct the investigation themselves, in order to remain impartial.

The Director or R&I (or delegee), will:

- Appoint the relevant person/s to investigate the allegation
- Direct the investigators on how the investigation should proceed, and what form it should take e.g. Interview/s, document reviews

As required advice, or involvement, from other departments will be requested:

- People Advisory Team (HR)
- Finance department, in the event of financial implications
- Local Counter Fraud Service at the Trust

The respondent/s will be given opportunity to respond to the allegation and can be accompanied by an appropriate work colleague, staff representative or Union representative if they so wish.

Thorough documentation of the investigation including, but not limited to, correspondence, minutes taken of interviews, reports of document reviews/audits, should be saved within an access restricted folder on the RDSU Drive. Only the Director of R&I and those conducting the investigation will have access to the relevant folder for each investigation. Progress of the allegation and investigation will be recorded on a 'Suspected Research Misconduct or Fraud Log' (appendix 1).

4.3 Outcome of Investigation

Upon conclusion of the investigation, the Director of R&I will make the decision on whether the matter needs to be taken further. The level, and manner, of escalation will be dependent on the nature of the allegation and the findings of the investigation, but may include (but not limited to):

- Initiation of formal processes within the Trust e.g. Fraud investigation by Trust Counter Fraud team, initiation of HR processes by Trust HR.
- Report to an external regulatory body e.g. MHRA
- Report to research Sponsor

If the outcome of the investigation is that there is no case to answer, the investigation will be concluded. The investigation may highlight that there is additional support or training required to individuals or teams. This will be provided through the most appropriate avenue.

Where it is found that there is no case to answer, and the investigation finds the allegations to have been made maliciously, it may be necessary for the complainant to face HR processes.

The outcome of the investigation will be shared with the complainant/s and the respondent/s of the allegation. The outcome will also be reported to the R&I Heads of Service group and the Trust Executive Director for R&I.

5. References

ICH GCP

ICH: E 6 (R2): Guideline for good clinical practice - Step 5

UK Policy Framework for Health and Social Care Research

UK Policy Framework for health and social care research

Medicines for Human Use (Clinical Trials) Regulations

The Medicines for Human Use (Clinical Trials) Regulations 2004

UK Research Integrity Office (UKRIO)

https://ukrio.org/

APPENDIX 1: Suspected Research Misconduct or Fraud Action Log

Date of initial contact	
Name of complainant/s (person/s making allegation) *(unless wishing to be anonymous)*	
Contact details of complainant/s (email & phone)	
Name of study & reference number involved (if known)	
Date/s of incident	
Name of person in R&I informed of the allegations *(if not direct approach to Director of R&I)*	
Date Director of R&I informed	
Details of allegations made: *What has happened? When did it happen? Who is involved?*	
Person/s appointed to investigate the allegation *Name and job title*	
Date investigators appointed	
Details of investigation *(repeat section as required)*	
Manner of investigation	*e.g. Interview, document audit etc*
Date of Investigation	*Date/s this investigation was performed*
Supporting documents	*Link to folder containing relevant documents e.g. interview minutes, audit reports etc*
Manner of investigation	
Date of Investigation	
Supporting documents	
Date R&I Investigation completed	
Outcome of Investigation	

Confirmation of completion of R&I investigation by Director of R&I (or delegee):	Signature:	
	Job Role:	
	Date:	