NHS
Gloucestershire Hospitals
NHS Foundation Trust

Pharmacovigilance 03 - Research Misconduct and Fraud

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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

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1 Introduction, Background and Purpose

The Trust expects all research involving their patients, staff and resources to be conducted according to the highest standards of research practice. This applies whether the organisation concerned is acting as the host and/or the sponsor of the research. In addition to ensuring that all regulatory requirements are met, researchers may wish to refer to more general guidance on good research practice such as:

i) Code of Practice for Research (UK Research Integrity Office, 2009)
ii) Guidelines on Good Research Practice (Wellcome Trust, Nov 2005)
iii) Good Research Practice: Principles and guidelines (Medical Research Council, July 2012)

While it is expected that an allegation of research misconduct will be a very rare event, research misconduct 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.

This SOP follows the principles and guidelines set out in the 'Procedure for the Investigation of Misconduct in Research' published by the UK Research Integrity Office (UKRIO) in August 2008.

The UKRIO is available to provide direct advice and guidance to all parties involved in an allegation of research misconduct. Contact details can be found on the UKRIO website at http://www.ukrio.org/get-advice-from-ukrio/

1.1 Definitions

Research Misconduct
The UK Research Integrity Office (RIO) defines research misconduct as including, but not limited to:

- Fabrication;
- Falsification;
- Misrepresentation of data and/or interests and/or involvement;
- Plagiarism;
- Failures to follow accepted procedures or to exercise due care in carrying out responsibilities for:
  a. avoiding unreasonable risk or harm to
    - humans;
    - animals used in research;
    - the environment;

  b. the proper handling of privileged or private information in individuals collected during the research

It goes on to say:

> '...misconduct in research includes acts of omission as well as acts of commission. In addition, the standards by which allegations of misconduct in research should be judged should be those prevailing in

the country in question and at the date that the behaviour under investigation took place' .

In order to reach the conclusion that misconduct has taken place, it must be judged that there was an intention to commit the misconduct and /or recklessness in the conduct of the research.

Complainant(s)
The complainant is the person making the allegation of research misconduct. A complainant may be anyone with a concern i.e. The complainant does not have to be a member of staff (past or present) of the organisation concerned.

Respondent(s)
The respondent is the person against whom the allegation is made.

Named Person (NP)
The named person is the individual nominated by the Trust with responsibility for:

- Receiving allegations of research misconduct
- Initiating and supervising the process for investigating the allegation
- Maintaining information about the allegation and its investigation and making the necessary reports within the organisation and to the appropriate external organisations
- Taking decisions at key stages of the procedure

1.2 Principles

Research misconduct is a serious matter but investigations of such an allegation within the Trust will be conducted in accordance with the UKRIO principles, including the presumption of innocence. These principles are:

- Fairness
- Confidentiality
- Integrity
- Prevention of detriment
- Balance

Further explanation of these principles can be found in Annex 1 of the UKRIO's 'Procedure for the Investigation of Misconduct of Research' (p 21 – 26 http://ukrio.org/publications/misconduct-investigation-procedure/).

All staff in the Trust should report any suspected misconduct as soon as they become aware of it.

The Trust will support people who raise concerns about the conduct of research in good faith and will not penalise them. However complainants making allegations that are malicious or vexatious rather than mistaken, may be subject to disciplinary proceedings.

The purpose of this SOP is to describe the procedures for investigating allegations of research misconduct within the Trust.

2 Who should use this SOP

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

3 When this SOP should be used

This SOP should be referred to when an allegation of research misconduct (as defined under paragraph 1.1) 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 organisations concerned and prior to use of an organisation's standard disciplinary procedure. Individuals using this SOP should also refer to any relevant statutory obligations of the organisation and legislation e.g. employment law and the Public Interest Disclosure Act 2013.

4 Procedure(s)

The procedure for investigating allegations of research misconduct follows the model procedure recommended by the UK Research Integrity Office (UKRIO) in their document 'Procedure for the Investigation of Misconduct in Research' published in August 2008. Details of the procedure can be found in Part C of the UKRIO's document (http://ukrio.org/publications/misconduct-investigation-procedure/) .

4.1 Preparatory Steps

The Trust should have in place nominated key individuals to assist in investigating allegations of research misconduct, should they arise.
These are:

i) 'Named Person' (and an alternate) and
ii) senior individuals from the relevant Personnel and Finance departments.

4.1.1 Named Person

The UKRIO advise that the 'Named Person' (NP) should be a person within the organisation with significant knowledge and experience of research but should not be

- the head of the organisation
- the head of research or
- the head of personnel.

It is not clear what is meant by 'head of research' but for the purposes of this SOP, the clinician who acts as R&D lead for an NHS member organisation would be acceptable as the NP. In the event of the NP having a conflict of interest, the designated 'alternate' would act in place of the NP in keeping with the UKRIO's procedure.

4.1.2 Personnel (HR) and Finance

In addition, the organisation should nominate senior individuals within the Personnel and Finance departments, ideally with some experience of research, to assist the NP in investigating allegations.

Contact details for the NP for the Trust can be found on the Research & Development website.

4.2 Procedure

The procedure below describes the process to be followed when an allegation has been received in writing by the NP. An initial enquiry from a complainant might be anonymous but in order for the allegation to be investigated it should be submitted in writing. Some situations may not require formal investigation but might be resolved by informal discussion and / or arbitration e.g. those that are not regarded as serious in nature. UKRIO will offer advice as to whether an informal resolution might be appropriate for a specific allegation.

There are four stages to the procedure for investigating an allegation;

- the preliminary stage,
- the pre screening stage,
- the screening,
- the formal investigation.

The NP should follow the detailed procedure for each of these stages as set out in Part C of the UKRIO's 'Procedure for the Investigation of Misconduct in Research' (2008).

A summary of the whole procedure is outlined below.

4.2.1 Preliminary stage

- An allegation of research misconduct should be submitted in writing to the NP in the relevant organisation. Receipt of the allegation should be formally acknowledged. If the NP has any involvement or potential conflict of interest in the case, the matter should be dealt with by the NP's designated alternate.
- The NP reviews the allegations to judge if the reported behaviour falls within the definition of research misconduct. Even at this stage it may be necessary to take immediate action to protect participants, staff etc and to

inform the relevant regulatory authorities. It may also be necessary to implement the organisation's disciplinary process. If so, this will continue in parallel with the investigation of the allegation of research misconduct.

- If the allegation falls outside the definition of research misconduct the NP (or alternate) will write to the Complainant to inform them of the reasons why the research misconduct investigation process is not appropriate, advise which process might be appropriate for handling the allegation and to whom it should be reported.
- If the allegation is deemed to fall within the definition of research misconduct, the NP informs the following people within the member organisation(s):
  - The Chief Executive
  - Director of R&D/ Board Lead for R&D
  - The Head of Personnel
  - The Head of Finance
- If the member organisation is the Respondent's primary employer the investigation proceeds. If the Respondent has a different primary employer, the allegation will be referred on to that employer.
- If contractual obligations apply, the NP informs other organisations involved in the research e.g. the funding body/ Sponsor.
- The NP informs the Respondent about the allegations made against him/her. The Respondent receives a summary of the allegations in writing and information about the procedure for investigating the allegation(s).

4.2.2 Pre screening Stage

- The NP ensures that relevant information and evidence is protected, especially if there is concern of risk to individuals or that evidence may be destroyed or tampered with. Such action may include securing medical records and research materials, temporary suspension of the Respondent, limiting his/her access to parts of the Organisation's premises. The Respondent must be informed of the reasons for these actions in writing.
- The NP may consider it appropriate to carry out additional investigations if related but separate issues of research misconduct come to light.

The Preliminary and Pre Screening stages should normally be completed within 10 working days of an allegation being received in writing.

4.2.3 Screening Stage

- The NP completes an initial investigation to determine that there is a case to answer i.e. the allegation is not mistaken, malicious, vexatious, or frivolous. If it is found to be any of the latter, the allegation will be dismissed. Under such circumstances a decision will be taken about the need for disciplinary action against the Complainant.
- If the allegation cannot be discounted at this point, a Screening Panel will be convened. The purpose of the Panel is to decide if there is a prima

facie case of misconduct (see Annex 4 of the UKRIO's document for guidance about the composition and operation of the Screening Panel).

- The Screening Panel should aim to issue draft findings to the NP within 30 working days of being convened. The NP should forward the draft findings to the Respondent and Claimant. A final report will be issued when any factual errors have been corrected.
- Allegations then considered to be mistaken, frivolous, vexatious and/or malicious will be dismissed. It may be necessary to take action to uphold the reputation of the Respondent and the relevant research project(s). Under these circumstances, a decision will also be made regarding the need for disciplinary action against the Complainant.
- When the allegations have some substance but are considered to be relatively minor and / or there was no clear intent to deceive, a formal investigation will not be required and the matter will be dealt with through the relevant education and training processes, or other non-disciplinary mechanisms, within the member organisation. The needs of staff and or students working with the Respondent should also be considered.

When there is considered to be substance to the allegations and they are sufficiently serious, a formal investigation will be implemented.

4.2.4 Formal Investigation

- The NP informs the following people that a formal investigation is taking place:
  - Respondent
  - Complainant
  - Chief Executive of the Trust
  - Head of Personnel
  - Head of Finance
  - Personnel in relevant external organisations e.g. funding bodies/ Sponsor
- The NP convenes a formal Investigation Panel (see Annex 5 of the UKRIO's guidance for advice about the composition and operation of the Investigation Panel).
- The Panel reviews the evidence and interviews the Respondent and Complainant.
- Having reviewed the evidence, the Investigation Panel concludes whether the allegation of research misconduct is:
- upheld in full
- upheld in part
- not upheld
- The NP, Head of Personnel and other appropriate senior members of the Trust decide what action should be taken.
- The NP informs the Respondent, Complainant, Heads of the Trust and relevant departments and relevant external bodies of the outcome and what actions are to be taken.
- The actions are implemented.

5. Other SOPs and Documents

The Trust will also have in place related policies and procedures that it may be appropriate to consult. For example procedures for reporting concerns about the performance of colleagues/ DATIX.

Procedure for the Investigation of Misconduct in Research, UK Research Integrity Office, August 2008
http://www.ukrio.org/publications/misconduct-investigation-procedure/

Flowchart of process to investigate Misconduct and/ or Fraud in Research