1. Introduction

This Standard Operating Procedure (SOP) describes the procedures required for management of suspected fraud and misconduct in research Hosted by the University Hospitals of Leicester NHS Trust (UHL)

Fraud and misconduct in research is rare, but it is serious. The investigation process for suspected or alleged fraud or misconduct must be managed in accordance with the highest standards of integrity, accuracy and fairness.

Individuals responsible for carrying out investigations of alleged fraud or misconduct must act with integrity and sensitivity at all times.

This document describes the specific procedures for dealing with suspected or alleged fraud and misconduct in research. It is not a stand-alone document and should be viewed in conjunction with other UHL SOPs and Policies as appropriate.

The outcome is that UHL fulfils its requirements to identify and manage all reports of suspected fraud and misconduct.

2. Scope

This SOP applies to ALL individuals involved in research hosted by the UHL A separate SOP exists dealing with suspected fraud and misconduct in research 'Sponsored' by the UHL.

3. Definitions

The definition of fraud and misconduct adopted by the Medical Research Council (MRC) is to be used:

> *"'The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research and deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others.*
>
> *It does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct (including gross misconduct) unrelated to the research process"* (MRC, 1997).

In addition to this the following is added for the purposes of this SOP:

It also includes intentional; unauthorised use; disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings or devices used in or produced by the conduct of research and information of a confidential nature.

4. Procedure

Suspected research fraud or misconduct may be reported in a variety of ways. No matter which avenue is used, a robust and thorough investigation must be carried out. Research fraud or misconduct is a rare but serious issue.

It is important to note that a research fraud and misconduct investigation is a separate and independent process and should not be confused with any action required following a routine audit or monitoring visit. Errors identified in routine audits and monitoring visits are to be managed using the SOP C-2013 UHL Non-Compliance SOP. It may be necessary to implement this SOP should it be suspected that issues of Non-Compliance are deliberate or negligent.

Where potential research fraud has been identified an assessment must be made as to whether or not a criminal offence has occurred. Guidance on whether the potential research fraud is contrary to the Fraud Act of 2006, the Bribery Act 2010 and other relevant legislation can be obtained from the UHL Counter Fraud Teams. Contact details of the UHL Counter Fraud Teams are available on the Insite pages of the Trust.

The Research & Innovation Directorate (R&I) is responsible for ensuring that all research hosted by UHL is conducted within the laws that exist in the UK. It does not have the authority alone to make decisions that may affect the employment status of an individual(s), therefore, while the R&I Directorate will lead investigations into suspected fraud and misconduct, every investigation will be managed in conjunction with Human Resources, and in accordance with HR Policies and Procedures.

4.1)
Identification of Suspected Fraud or Misconduct

Any individual within UHL or a member of the public may report suspected fraud or misconduct to any member of a research team, to a member of the R&I Team or through the UHL 3636 Raising Staff Concerns dedicated line. It is also possible that concerns of fraud and misconduct be identified during routine monitoring or audits, or through a regulatory authority inspection.

On receiving notification or identifying that fraud or misconduct in research is suspected, the individual receiving the allegation must immediately pass all detail obtained to the Head of Research Operations or Assistant Director of R&I.

On receiving an allegation of suspected fraud or misconduct it is essential that no comments are made about the allegation. It is important to remember that at this stage no investigation has taken place. The contact details and name of the individual making the accusation should be taken where possible.

If an allegation is being made by an individual who wishes to remain anonymous, as much detail as possible should be obtained at original contact.

On receiving notification of an allegation, the Head of Research Operations will, where possible, contact the individual making the allegation and arrange a mutually convenient time to meet face to face if possible, to discuss the detail. Where possible, this should occur within two (2) calendar days of the original allegation.

4.2)
Initial Investigation of Suspected Fraud or Misconduct

On receiving information about an allegation of suspected fraud or misconduct the Head of Research Operations or Asst. Dir. R&I must immediately make an assessment about the nature of the allegation. An initial telephone conversation or where possible a face to face meeting with the individual making the allegation must be made as soon as possible, but within two (2) calendar days of the original notification. Initial details must be obtained during the telephone conversation

or meeting to ascertain the nature of the allegation using Appendix 1 – Suspected Fraud or Misconduct Initial investigation template.

Where it is deemed highly likely, or very possible that patients, staff, premises or data are at risk, the Head of Research Operations or Asst. Dir. R&I will urgently discuss the allegation with the Director of R&I. If the Director of R&I is not available, a Director of HR, Medical Director, or another appropriate Director will be consulted. Following consultation and agreement, the Head of Research Operations or Asst. Dir. of R&I will take steps appropriate to suspend research activity. This may involve suspending one research study or all studies related to an individual. Appropriate steps must be taken to notify the relevant Sponsor, & Regulatory Authorities of the decision to temporarily suspend activity, pending an investigation of alleged research fraud or misconduct. It is important to recognise that swift action is often required.

Following this initial assessment and information gathering, the Head of Research Operations or Asst. Dir. R&I must notify Human Resources. Notification must be made to relevant HR Lead and the R&I Lead of the relevant Clinical Management Group (CMG).

All communication about the alleged fraud or misconduct must be copied to the HR Lead as well as the Head of Research Operations or Asst. Dir. R&I.

4.3)
Full Investigation of Suspected Fraud or Misconduct
Once an assessment of immediate risk has been completed and appropriate immediate action taken, it is essential that a full investigation of the allegation is undertaken as quickly as possible.

The length of the investigation will depend on the number of individuals involved, but everyone who has involvement must be included in the investigation. The investigation will be conducted in the form of interviews which will be formally conducted with written notes taken at each interview. The notes will not be written verbatim but will form an accurate account of the questions asked and the answers given. The interviews will be led by the Head of Research Operations or the Asst. Dir. R&I, and will be attended by an HR representative, where necessary, the R&I Lead of the CMG or their representative, and an independent note taker present.

Individuals to be interviewed will be contacted to arrange a mutually convenient time and location. A letter will be sent to confirm the details of the interview, copied to all due to attend the interview. The wording of the letter will be determined in association with HR, but interviewees will always be offered the opportunity to attend with a personal representative.

At the end of each interview, the individual will be given the opportunity to ask any questions. Notes will be written up and sent to the individual for their comment within 72 hours of the interview. Where an individual disputes the content, they will be asked to outline the differences and return them to the Head of Research Operations or Asst. Dir. R&I and the HR representative. Where possible, agreement will be reached on the content of the notes, and the individual will be asked to sign and date confirming their agreement and accuracy of the content. Where agreement cannot be reached, signatures will not be obtained, but all versions of the notes will be collated as part of the investigation documentation.

During the interviews other documentation may be referred to. These documentation must be provided to the Head of Research Operations or Asst. Dir. R&I and will be used as evidence during the investigation. These documents may be shown to other individuals during interviews where it is deemed appropriate. Evidence must be catalogued and appended as relevant to the interview notes which will also form part of the evidence.

Interview notes must be recorded on Appendix 2 – Suspected Fraud and Misconduct Interview Template.

Documented evidence must be recorded on Appendix 3 – Suspected Fraud and Misconduct Evidence Listing Template.

It is recognised that attending an interview about alleged research fraud or misconduct can be stressful even where there is no case to answer. All the appropriate support mechanisms will be offered to all personnel involved in the investigation.

4.4)
Conclusion of Full Investigation of Suspected Fraud or Misconduct
Once all necessary interviews have taken place, and where possible notes have been confirmed and signed, the Head of Research Operations or Asst. Dir. R&I and HR Representative will make a decision about the investigation.

There are two possible outcomes:

- Case to Answer
- No Case to Answer

4.4.1)
Case to Answer
If the evidence provided, and obtained through interview show that there is a case to answer, the investigation evidence will be provided as a Dossier to the HR Representative. The HR Representative will take the matter further in accordance with the relevant HR and Employment Policies. The further action will be dependent on the nature of the allegation and the evidence provided. Every individual involved in the investigation will be notified of the outcome and will be instructed as appropriate by HR. The Head of Research Operations or Asst. Dir. R&I may, if deemed appropriate, be part of the further HR Investigation.

A decision will be made about the status of the studies and whether or not it is appropriate that they remain suspended. A brief update will be required for the Regulatory Agencies which will be provided by the Head of Research Operations or Asst. Dir. R&I in collaboration with the HR Representative.

4.4.2)
No Case to Answer
If the evidence provided, and obtained through interview show that there is no case to answer, the investigation will be concluded. Every individual involved in the investigation will be notified of the outcome. It may be that there is additional support or training required as a direct result of the investigation. This will be provided as appropriate through the most appropriate avenue.

A decision about reinstating the studies if they have been suspended will be made in communication with the Principal Investigator & Sponsor. An update will be required for the Regulatory Agencies which will be provided by the Head of Research Operations or Asst. Dir. R&I in collaboration with the HR Representative.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	Person identifying potential misconduct or fraud	Person identifying potential misconduct or fraud	Notify Head of Research Operations or Asst. Dir. R&I immediately when they become aware of alleged research misconduct or fraud
2	Research Office	Head of Research Operations / Asst. Dir. R&I	Conduct initial investigation and take necessary steps to ensure safety. Communicate as necessary and appropriate with relevant regulatory authorities.
3	Research Office	Head of Research Operations / Asst. Dir. R&I	Contact HR and relevant CMG R&I Lead to notify them of the allegation
4	Research Office	Head of Research Operations / Asst. Dir. R&I	Lead Investigation in collaboration with HR. Provide independent note taker
5	Research Office	Head of Research Operations / Asst. Dir. R&I	Complete dossier of evidence and provide same to HR
6	Research Office	Head of Research Operations / Asst. Dir. R&I	Pass dossier to HR where there is a case to answer and be available as part of the ongoing action
7	Research Office	Head of Research Operations / Asst. Dir. R&I	Arrange appropriate training and support where there is no case to answer. Retain dossier for information.

6. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

7. Education and Training

The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

8. Education and Training

None

9. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Sponsor Audit	Randomly chosen for audit	Carolyn Maloney	As and when	A report will be produced

10. Supporting Documents and Key References

SOP C-2016 Appendices 1, 2 & 3

SOP C-2013

11. Key Words

Research, Innovation, EDGE, REC, Fraud, Misconduct, Suspected, Non-Compliance

12. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

14.

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This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

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Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
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