

Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster CCG	Page 1 of 5
Research Management & Governance	SOP No. RM&G0017, Version 1
Research Fraud and Misconduct	Supersedes: Not applicable
	Attachments: None
	Effective date: 29th November 2013

Signatures:

Role	Name	Function	Date (DD-MM-YYYY)	Signature
Author	Amy Beckitt	Clinical Research Development Manager	27-11-2013	
Reviewer	Dr Trevor Rogers	Director of Research and Development	28-11-2013	

Reviewed every 2 years unless changes to applicable legislation require otherwise

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1.0 Definitions

Please refer to the current version of the SOP RM&G0002 for a glossary of all terms and acronyms.

Research Misconduct - The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research and deliberate, dangerous or negligent deviations from accepted practice 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.

(Glossary taken from the Medical Research Council)

2.0 Purpose

The purpose of this SOP is to cover the procedures surrounding the management of suspected research fraud and misconduct for research within Doncaster and Bassetlaw Hospitals NHS Foundation Trust. For the purpose of this SOP the 'Trust' shall henceforth refer to Doncaster and Bassetlaw Hospitals NHS Foundation Trust.

The Trust expects all research undertaken with patients, staff or resources to be conducted in accordance with the highest standards of research practice. Research misconduct is entirely unacceptable, and it is essential there is a clear Trust process for legitimate concerns to be raised, investigated and where appropriate, acted upon in a fair and transparent manner.

3.0 Scope

This SOP covers all personnel who are involved in research studies taking place within the Trust, irrespective of the organisation acting as the study sponsor. The procedure described in this SOP should be followed where allegations of research misconduct are made against Trust personnel. In the case of an allegation being made against an honorary contract or a letter of access holder, advice will be sought from the employing organisation of the individual against whom the allegation is made.

4.0 Procedures

All Trust personnel, including those holding an honorary contract or a letter of access, have a duty to report observed, suspected or apparent research misconduct. Incidents of research misconduct may be identified in various ways, including through the Trust 'Whistleblowing Policy', an internal study audit or an externally led audit or inspection. The process is as follows:

1. An allegation of research misconduct should be submitted in writing to the Director of Research and Development (R&D) as soon as identified, and will be acknowledged in writing by the Director of R&D. Where the written allegation concerns the Director of R&D or a potential conflict of interest is identified, the allegation will be brought to the immediate attention of the Medical Director. As far as it is reasonably practicable, the confidence of the person making the allegation will be protected, but where action of a disciplinary/criminal nature is being contemplated, evidence may need to be given in person and/or in writing.

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2. The Director of R&D will review the allegation to assess whether the incident falls within the scope of the definition of research misconduct detailed in this SOP. If the Director of R&D determines the allegation does not constitute research misconduct, s/he will write to the person submitting the allegation and detail the reasons as to why the misconduct investigation is not appropriate. The person submitting the allegation will be directed towards the appropriate Trust policy if to provide any support or alternative means of addressing the issue identified.
3. Where the misconduct investigation is appropriate, the Director of R&D will appoint a relevant person or persons to conduct this. The Director of R&D will decide how the initial investigation should take place and in what form. The Director of R&D will inform the Medical Director of the ongoing initial investigation, and seek advice from Human Resources as appropriate. In the event of financial implications, the Director of Finance, Information & Procurement will be informed of the ongoing initial investigation.
4. The Director of R&D will write to the staff member against whom the allegation has been made to inform them of the nature of their alleged conduct or behaviour, and that a preliminary investigation is taking place. The Director of R&D will take reasonable steps to ensure that any relevant information and evidence is appropriately protected, especially if there is a concern of risk to individuals or that evidence may be destroyed or tampered with. This will be communicated to the staff member against whom the allegation has been made, along with a reminder of their right of access to support and advice from their trade union.
5. A 'Case to Answer' report of the preliminary investigation will be prepared for the Director of R&D within 5 working days of the investigation request. The Director of R&D will decide whether there are grounds for proceeding further. Initial action will be taken as appropriate, which may include the suspension of research related to the staff member against whom the allegation has been made. In this instance, the relevant regulatory authorities will be notified in the appropriate timeframe, for Trust sponsored research. For externally sponsored research, the study sponsor will be informed of the action taken.
6. Where there are grounds for proceeding further, a full investigation will be conducted in accordance with the Trust 'Whistleblowing Policy'. If a serious allegation of research misconduct is made and is supported by credible evidence, then the Trust has a duty to report this to any external body in accordance with Trust policy. There may be possible sanctions outside of the Trust general disciplinary procedures where research misconduct is proven. There is a right of appeal as outlined within the Trust 'Whistleblowing Policy'. In the event of allegations not being substantiated, there should be appropriate steps taken towards restoration of reputation.

Related SOPs and Documents

1. Trust policy CORP/EMP 14: 'Whistleblowing Policy: Voicing your concerns'