Research Misconduct Policy

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What is in this policy?
This policy describes how research misconduct it handled at University Hospitals Bristol and Weston NHS Foundation Trust (the Trust). Research Misconduct is managed in line with the Trust's Freedom to Speak up and Disciplinary Policies. This Research Misconduct Policy clarifies the definition of Research Misconduct, the responsibilities for investigating allegations and possible sanctions relating to cases of Research Misconduct. It is to be used by all staff (including those with honorary contracts or other HR arrangements in place) who are undertaking research at or on behalf of UHBW.

Document Change Control				
Date of Version	**Version Number**	**Lead for Revisions**	**Type of Revision**	**Description of Revision**
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Sign off Process and Dates	
Groups consulted	**Date agreed**
Director of Research	26/05/2025
Policy Assurance Group	11/06/2025
Clinical Quality Group	15/10/2025

- **Stakeholder Group** can include any group that has been consulted over the content or requirement for this policy.
- **Steering Group** can include any meeting of professionals who has been involved in agreeing specific content relating to this policy.
- **Other Groups** include any meetings consulted over this policy.
- **Policy Assurance Group** must agree this document before it is sent to the **Approval Authority** for final sign off before upload to the DMS.

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Do I need to read this Policy?

All Staff (including those with honorary contracts or other HR arrangements in place) who are undertaking or supporting research at UHBW must be aware of the Policy.

Sections 6 and 7 of this Policy should be read by all managers with oversight and responsibility for the research function.

All research staff must also read

The UHBW Research Policy, and
Research Standard Operating Procedures as applicable to their role.

1. Introduction

This policy describes how research misconduct is managed within the Trust.

2. Purpose

The purpose of this document is to define and clarify the potential causes of Research Misconduct and clarify the Trust procedures for:

- The reporting of allegations of Research Misconduct in line with the Trust's Freedom to Speak Up Policy (7822)
- The investigation of such reports in line with the Trust's Respecting Everyone Policy (27301)
- The reporting of allegations and investigation of suspicions of fraud in line with the Trust's Local Counter Fraud, Bribery and Corruption Policy (13274)

3. Scope

This policy applies to all staff (including those with honorary contracts or other HR arrangements in place) who are undertaking research at the Trust. It relates to all research falling under the UK Policy Framework for Health & Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations, and any research funded by a research grant from a local, national or international funder that falls outside the scope of this framework.

4. Definitions

4.1 Research Misconduct

"Research Misconduct" includes the following, deliberate, reckless, or negligent actions:

- failure to obtain appropriate permission to conduct research;
- deception in relation to research proposals;
- unethical behaviour in the conduct of research, for example in relation to research participants;
- bribery or corruption in relation to research
- unauthorised use of information which was acquired confidentially;
- deviation from Good Clinical Practice, where this results in unreasonable risk of harm to humans;
- fabrication, falsification, or corruption of research data;
- distortion of research outcomes, by distortion or omission of data that do not fit expected results;
- dishonest misinterpretation of results;
- publication of data known or believed to be false or misleading;
- plagiarism, or dishonest use of unacknowledged sources;
- misquotation or misrepresentation of other authors;
- inappropriate attribution of authorship;
- attempting, planning, or conspiring to be involved in research misconduct;
- inciting others to be involved in research misconduct;
- collusion in or concealment of research misconduct by others;
- failing to declare or appropriately manage conflicts of interest;
- undertaking regulated activity when you are barred from such activity;
- failing to declare your removal from a professional register by a regulatory body, or conditions placed on your registration, where your role in a research study requires a professional registration.

- fraud or other misuse of research funds or research equipment which may be dealt with under the Trust's Local Counter Fraud, Bribery and Corruption Policy (13274)

4.2 Sponsor

All health and social care research must have a sponsor as defined in the UK Policy Framework for Health and Social Care Research. The sponsor is

'the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project'
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/#sponsors

5. Duties, Roles and Responsibilities

5.1 Chief Executive

The Chief Executive has overall responsibility for the integrity and conduct of clinical research conducted within the Trust.

5.2 Trust Medical Director

The Trust Medical Director/Responsible Officer has delegated authority and is responsible for ensuring that this policy is approved and followed by staff working within the Trust and that it is reviewed in a timely manner. Also, that it complies with The Medical Profession (Responsible Officers) (Amendment) Regulations 2013.

5.3 Director of Research

The Director of Research has delegated authority and is responsible for working with the Deputy Director of Research/Head of Research and Development to ensure that all concerns are addressed in an appropriate manner.

5.4 Deputy Director of Research/Head of Research and Development

The Deputy Director of R&D is responsible for receipt of concerns with regard to possible Research Misconduct and for ensuring that such concerns are investigated and followed up to conclusion.

5.5 All Staff

All employees of the Trust including those with honorary contracts (including clinical and research honorary contracts) have a responsibility to report any incident of misconduct whether this has been witnessed or suspected.

6. Policy Statement and Provisions

6.1 Need for the Policy

6.1.1 The UK Policy Framework for Health and Social Care Research v3.3 dated 07/11/2017 states that employers of the chief investigator and members of the research team are expected to "*take proportionate, effective action in the event of errors and breaches or if misconduct or fraud are suspected*."

6.1.2 The Concordat to Support Research Integrity (Universities UK) declares that employers of researchers are responsible for *"demonstrating that they have procedures in place to ensure that research is conducted in accordance with standards of best practice; systems to promote research integrity; and transparent, robust and fair processes to investigate alleged research misconduct."*

6.1.3 In addition, the Researcher Development Concordat (Universities UK) states that researchers must "*use available mechanisms to report staff who fail to meet the expected standards of behaviour, particularly in relation to discrimination, harassment, bullying, and research misconduct.*"

6.1.4 It is also a recommendation of good practice that all NHS Trusts undertaking, sponsoring, funding, and hosting research have a clear Board-approved policy that includes the identification and handling of Research Misconduct.

6.2 Procedures

The Trust expects all its employees to observe the highest standards in the conduct of their research and in pursuance of such high standards it is expected that they will: 5.1.1 Take steps to acquaint themselves with available guidance as to "best practice" whether in relation to matters of research policy, finance, or safety relevant to their area of research e.g. the UK Policy Framework for Health and Social Care Research; the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments.

6.2.1 Observe such legal, ethical, managerial, and training requirements as are laid down by the Trust or by Health Research Authority (HRA) or other appointed bodies involved in their field of research.

6.2.2 Take steps to ensure the safety of those associated with the research.

6.2.3 Report any conflict of interest, whether actual or prospective, to the Trust. Please see also the Trust's Declaration of Interest Policy (CO-10).

6.2.4 Observe fairness and equity in the conduct of their research.

6.2.5 Comply with the requirements of an individual's Professional Registration, as set out by their Professional Body/Council, where relevant.

6.2.6 Failure to comply with the policy may give rise to an allegation of misconduct in research. Research Misconduct may be grounds for disciplinary action and, if serious, may be considered as gross misconduct which can result in dismissal or withdrawal of an honorary contract with the Trust.

6.3 Confidentiality

6.3.1 Suspicions reported in confidence and in good faith, even if proven to be unfounded, will not lead to disciplinary proceedings against the person raising the concern and the Trust's Freedom to Speak Up Policy (7822) will apply for qualifying disclosures. However, in the event of a malicious allegation, appropriate action will be taken.

6.3.2 All allegations will be investigated in the strictest confidence. All those who are involved in the procedures for investigating an allegation including witnesses, representatives and people providing information, evidence and/or advice have a duty to maintain confidentiality.

6.3.3 However, for an allegation to be investigated fully and appropriate action taken, it may be necessary to disclose the identity of the complainant to the person who is the subject of the complaint. The complainant will be advised before such disclosure is made.

6.3.4 In cases of possible, suspected, serious Research Misconduct, the Trust may have a contractual requirement to inform the research funder/s and research Sponsors (if applicable) of the allegation and keep the funder/s and Sponsor informed of progress with the investigation.

6.3.5 In cases where the allegation involves an honorary appointee, the staff member's substantive employing organisation may be informed of the allegation and subsequent investigation, as appropriate.

6.4 Procedure in the Case of Suspected Misconduct in Research

6.4.1 These procedures are without prejudice to the normal operation of the relevant disciplinary procedures of the Trust (Respecting Everyone Policy (27301). They are set out by way of guidance only and may be varied to suit the circumstances of a particular case. In the event of any conflict between these procedures and the relevant disciplinary procedure of the Trust, the latter shall take precedent.

6.4.2 Reports of Research Misconduct, either witnessed or suspected, should be made directly to, or escalated to, the Deputy Director of Research in the first instance; if the deputy director is the subject of the report then the Director of Research should be informed in the first instance.

6.4.3 On receiving the allegation, the Deputy Director of Research will assess whether any immediate action is required to prevent further risk or harm to employees, research participants or the Trust or immediate action required to protect data and research integrity.

6.4.4 This will be followed by a preliminary investigation led by the Deputy Director of Research, or nominated Research & Development Senior Team representative, to determine whether: there is no substance in the allegations and therefore no further action is necessary; the case has substance but does not meet the threshold of research misconduct and can be dealt with outside of this policy or if there is evidence of Research Misconduct, which would need to be referred to the Director of Research and Chief Medical Officer. Any suspicions/allegations relating to fraud will be referred to the Loal Counter Fraud Specialist prior to preliminary investigations being undertaken and may result in parallel investigation alongside any misconduct investigation

6.4.5 In the event of there being a case to answer, the investigation of such reports will occur in line with the Trust's Respecting Everyone Policy (27301).

6.4.6 Where an allegation of Research Misconduct is being formally investigated, the Director of Research/Chief Medical Officer will make a decision whether to suspend the research and if it is appropriate to inform the Sponsor (as defined in the UK Policy Framework for Health and Social Care Research) of the ongoing investigation.

6.4.7 As well as sanctions identified within Trust Disciplinary Policy, other sanctions, through the authority of the Director of Research, may include:

6.4.7.1 Withdrawal of pending grant submissions led by the individual concerned.

6.4.7.2 Withdrawal of the individual concerned from co-applicant roles on partner grants.

6.4.7.3 Withdrawal of Confirmation of Capacity and Capability for continuation of a research project and, possibly, any research projects in which the individual concerned has involvement.

6.4.7.4 Withdrawal of pending abstracts and papers from the research in question.

6.4.7.5 Submission of a Letter of Apology and/or Expression of Concern, Retraction or Withdrawal request for published abstracts and papers from the research in question.

6.4.7.6 Changes in staffing to relevant research project/s.

6.4.7.7 More frequent auditing and closer monitoring of future work.

6.4.7.8 Barring the individual concerned from conducting research in the Trust for a given period

6.4.7.9 Revoking an honorary research contract.

6.4.8 Where a researcher feels that they have been unfairly sanctioned, this should be addressed through the Trust grievance procedures.

6.4.9 In the case of misconduct, professional groups may also be subject to disciplinary action by their professional bodies. Doctors are responsible to the General Medical Council for their professional conduct as researchers, as well as clinicians. Similarly, nurses, health visitors and midwives are responsible to the Nursing and Midwifery Council.

6.4.10 In the case of misconduct, the Sponsor will be informed and will be responsible for reporting the misconduct to REC/HRA, if it is appropriate to do so.

6.4.11 In the case of misconduct related to involvement in Clinical Trials of Investigational Medicinal Products or Devices, this will be reported to the Sponsor who will be responsible for reporting the misconduct to the Medicines and Healthcare products Regulatory Authority, if it is appropriate to do so.

6.4.12 Attention will be drawn to this policy as a condition of Sponsor approval and/or Confirmation of Capacity and Capability.

6.4.13 The Trust is committed to reducing and preventing fraud, bribery and corruption in the NHS and ensuring that funds stolen by these means are put back into patient care. During the development of this policy document, we have considered how fraud, bribery or corruption may occur in the research environment. We have ensured that processes will assist in preventing, detecting, and deterring fraud, bribery and corruption and considered what our responses to allegation of incidents of any such acts would be.

In the event that fraud, bribery, or corruption is reasonably suspected, and in accordance with the Local Counter Fraud, Bribery and Corruption Policy, the relevant Team will refer the matter to the Trust's Local Counter Fraud Specialists for investigation and reserve the right to prosecute where fraud, bribery or corruption is suspected to have taken place. In cases involving any type of loss (financial or other), the Trust will take action to recover those losses by working with law enforcement agencies and investigators in both criminal and/or civil courts.

7. Standards and Key Performance Indicators

7.1 Applicable Standards

The Research Policy is supported and driven by the UK legal and regulatory framework for research, and by The Concordat to Support Research Integrity (Universities UK):

7.1.2 UK Policy Framework for Health & Social Care Research 2017.

7.1.3 The Concordat to Support Research Integrity (Universities UK, 2019)

In addition:

7.1.4 In addition, the Researcher Development Concordat (Universities UK, 2019)

7.1.5 Other regulations which have a bearing on the conduct of research are referenced in relevant Trust policies and procedures.

7.2 Measurement and Key Performance Indicators

Key performance indicators (KPI) for research are defined and agreed by the Director of Research in consultation with relevant Trust groups and committees. Performance against KPIs and standards is monitored in accordance with the table in section 10. For this Research Misconduct Policy; cases are rare but would be recorded appropriately in Research and Development.

8. References

UK Policy Framework for Health and Social Care Research v3.3 07/11/17 and any amendments.
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/

Researcher Development Concordat (Universities UK, 2019)
https://www.universitiesuk.ac.uk/what-we-do/policy-and-research/publications/concordat-support-research-integrity

Researcher Development Concordat (Universities UK, 2019)
https://researcherdevelopmentconcordat.ac.uk/

9. Associated Internal Documentation

Related policies are available at: https://uhbw.mystaffapp.org

- UHBW Freedom to Speak Up Policy (7822)
- UHBW Respecting Everyone Policy (27301)
- UHBW Research Policy (4158)
- UHBW Local Counter Fraud Bribery and Corruption Policy (13274)

10. Appendix A – Monitoring Table for this Policy

The following table sets out the monitoring provisions associated with this policy.

Objective	Evidence	Method	Frequency	Responsible	Committee
Monitoring of incidents to identify learning.	Incident reports from R&D	Data extraction from R&D	Quarterly, Annually and Ad hoc as required.	Senior Management Team (R&D)	Trust Research Group

Objective	Evidence	Method	Frequency	Responsible	Committee

Objective	Evidence	Method	Frequency	Responsible	Committee
To assess whether governance standards are being met and whether we are meeting performance standards.	Key Performance Indicators & standards associated with research projects	Report	Quarterly	Research Management Office	Trust Research Group
To advise SLT where KPIs are not being met	KPI exception report	Report	Monthly	Director of Research	Senior Leadership Team
To inform Trust Board of research activity and performance	Board report	Report	Biannual	Director of Research	Trust Board
To assure the trust of adherence to quality standards	Monitoring reports	Monitoring visits for individual research projects	Ad hoc	R&D staff responsible for monitoring	R&D department
To assure the trust of adherence to quality standards	Monitoring reports	Monitoring for individual research projects	Ad hoc	Principal Investigator/ nominated team member	R&D department
To maintain oversight of performance against KPIs	KPI review	Presentation of key performance indicators against plan	Monthly	R&I Operations Team	(Deputy) Director of Research
To assure NIHR of sound management of awarded funds	Financial information (spend against budget)	Report	Annual	Finance department	National Institute for Health Research

11. Appendix B – Dissemination, Implementation and Training Plan

The following table sets out the dissemination, implementation and training provisions associated with this Policy.

Plan Elements	Plan Details
The Dissemination Lead is:	Deputy Director of Research
Is this document: A – replacing the same titled, expired policy, B – replacing an alternative policy, C – a new policy:	C
If answer above is B: Alternative documentation this policy will replace (if applicable):	
This document is to be disseminated to:	Research Staff
Method of dissemination:	The Policy will be hosted on MyStaffApp and on Research and Development Sharepoint site.
Is Training required:	No
The Training Lead is:	N/A

Additional Comments

12. Appendix C – Equality Impact Assessment (EIA) Screening Tool

Further information and guidance about Equality Impact Assessments is available here:
http://nww.avon.nhs.uk/dms/download.aspx?did=17833

Query	Response
What is the main purpose of the document?	To describe how research misconduct is managed within the Trust
Who is the target audience of the document? Who is it likely to impact on? (Please tick all that apply.)	Add ☑ or ☒ **Staff**

Could the document have a significant **negative** impact on equality in relation to each of these characteristics?	YES	NO	Please explain why, and what evidence supports this assessment in relation to your response.
Age (including younger and older people)		√	No detriment identified

Disability (including physical and sensory impairments, learning disabilities, mental health)		√	No detriment identified
Gender reassignment		√	No detriment identified
Pregnancy and maternity		√	No detriment identified
Race (includes ethnicity as well as gypsy travelers)		√	No detriment identified
Religion and belief (includes non-belief)		√	No detriment identified
Sex (male and female)		√	No detriment identified
Sexual Orientation (lesbian, gay, bisexual, other)		√	No detriment identified
Groups at risk of stigma or social exclusion (e.g. offenders, homeless people)		√	No detriment identified
Human Rights (particularly rights to privacy, dignity, liberty and non-degrading treatment)		√	No detriment identified

Could the document have a significant positive impact on inclusion by reducing inequalities?	**YES**	**NO**	**If yes, please explain why, and what evidence supports this assessment.**
Will it promote equal opportunities for people from all groups?		√	
Will it help to get rid of discrimination?		√	
Will it help to get rid of harassment?		√	
Will it promote good relations between people from all groups?		√	
Will it promote and protect human rights?		√	

On the basis of the information/evidence so far, do you believe that the document will have a positive or negative impact on equality? (Please rate by circling the level of impact, below.)

Positive impact				**Negative Impact**		
Significant	Some	Very Little	**NONE**	Very Little	Some	Significant

Will the document create any problems or barriers to any community or group? NO

Will any group be excluded because of this document? NO

Will the document result in discrimination against any group? NO

If the answer to any of these questions is YES, you must complete a full Equality Impact Assessment.

Is a full equality impact assessment required? NO

Date assessment completed: 21/02/2025

Person completing the assessment: Research Grants Manager

13. Appendix D – Evidence of Learning from Incidents

The following table sets out any incidents/ cases which informed either the creation of this document or from which changes to the existing version have been made.

Incidents	Summary of Learning
North Bristol NHS Trust (NBT) had an audit from National Institute for Health and Care Research (NIHR), who are the main funder of UHBW research	One of the findings from the NBT audit by NIHR was that NBT did not have a formal Research Misconduct Policy. NBT now have this policy, and have shared with UHBW. This UHBW Research Policy aligns with that of NBT.