APPENDIX 6

Integrity in Clinical Research Policy & Procedure
Version 4.0

Category:	Policy
Summary:	The Trust expects that all clinical research will be conducted to the highest standards. This policy sets out standards for good clinical practice in research and describes the procedure for dealing with misconduct in research.
Equality Impact Assessed:	July 2024
Valid From:	July 2024
Date of Next Review:	July 2027
Approval Date/ Via:	Trust Management Executive 01 August 2024
Distribution:	Trust-wide
Related Documents:	Respect and Dignity at Work (Preventing Bullying and Harassment) Procedure Resolution (Grievance and Collective Disputes) ProcedureDeclaration of Interests Gifts Hospitality Sponsorship policy Incident Reporting, Investigation and Learning Procedure
Author(s):	Head of R&D Governance
Further Information:	Head of R&D Governance (Shahista.hussain@ouh.nhs.uk)
This Document replaces:	Integrity in Research Policy Version 3.0

Lead Director: Director of R&D

Issue Date: 01 August 2024

This document is uncontrolled once printed.

It is the responsibility of all users to this document to ensure that the correct and most current version is being used.
This document contains many hyperlinks to other related documents.
All users must check these documents are in date and have been ratified appropriately prior to use.

Document History

Date of revision	Version number	Author	Reason for review or update
04/06/2014	2.0	Lead of reseaech and Development	General update, incorporating revalidation
29/08/2017`	3.0	Head of R&D Governacne	General review and update
06/07/2024	4.0	Head of R&D Governance	General review and updates Updated rsk assessment

Consultation Schedule (This is a mandatory heading)

Use this table to evidence your involvement of staff and key stakeholders, where appropriate, in the development and review of documents.

Who? Individuals or Committees	Rationale and/or Method of Involvement
Katie Flight - Deputy Head of R&D Governance	Review of the document and changes
Jo Franklin – Senior Research Support Manager	Review of the document and changes
Lousie Willis – Research Support Manager	Review of the document and changes

Endorsement (This is a mandatory heading)

Use this table to list relevant Divisional and/Directorate leads who have endorsed the policy/procedural document.

Endorsee Job Title
Head Of R&D Operations
Director of R&D

Contents

Who should read this document?.

1. This policy applies to all areas of the Trust, and all employees of the Trust, including individuals employed by a third party, by external contractors, as voluntary workers, as students, as locums or as agency staff.

Key Standards/Messages

2. The Trust expects all its employees and those with honorary contracts to observe the highest standards in the conduct of their research and in pursuance of such high standards it is expected that they will:

    2.1. 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. UK Policy Framework for Health and Social Care (2017); Medicines for Human Use (Clinical Trials) Regulations and subsequent amendments.
    2.2. 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.
    2.3. Take steps to ensure the safety of those associated with the research.
    2.4. Report any conflict of interest, whether actual or prospective, to the Trust.
    2.5. Observe fairness and equity in the conduct of their research.
    2.6. Comply with the requirements of Medical Revalidation as set out by the General Medical Council (GMC) and ensure that all clinical research studies undertaken are declared and evidenced in the annual medical appraisal in line with GMC guidance (medical staff only).

3. Failure to comply with the policy may give rise to an allegation of misconduct in research. Misconduct in research 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.

Background/Scope

4. The UK Policy Framework for Health and Social Care (2017) states that there should be 'systems in place to detect and deal with research misconduct'. 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.

Key Updates

5. General review and updates.

6. The Equality Impact Assessment has been updated to the new template version.

Aim

7. The purpose of this document is to ensure that there is a procedure in place for:

    7.1. The reporting of concerns regarding the conduct of clinical research within the Trust.

    7.2. The investigation of such reports.

Content of the Policy

Confidentiality

8. Suspicions reported in confidence and in good faith will not lead to disciplinary proceedings against the person making the complaint and the

9. Freedom to Speak Up Policy will apply for qualifying disclosures. However, in the event of a malicious allegation, appropriate action will be taken.

10. 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.

11. 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.

Procedure in the Case of Suspected Misconduct in Research

12. These procedures are without prejudice to the normal operation of the relevant disciplinary procedures of the Trust (Conduct/Disciplinary Action Procedure and Performance Management Procedure for Medical Staff). 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.

13. Reports of misconduct, either witnessed or suspected should be made to the Head of R&D Governance in the first instance.

14. On receiving the allegation, the Head of R&D Governance will assess whether any immediate action is required to prevent further risk or harm to employees, research participants or the Trust.

15. This will be followed by a preliminary investigation to determine whether: there is no substance in the allegations and therefore no further action is necessary; the case is a minor one and can be dealt with on an informal basis, or if there is a serious case to answer, in which case the issue will be referred to the Head of R&D Operations/Director of R&D.

16. In the event of there being a serious case to answer the following Trust policies will be followed: Conduct/Disciplinary Action Procedure; Performance Management Procedure for Medical Staff; Raising Concerns (Whistleblowing) Policy.

17. The Head of R&D Operations/Director R&D will normally wish to have a discussion with the researcher involved and the individual is expected to make them available as a matter of urgency. The relevant HR officer will be contacted to ensure that a case manager is appointed. The conclusion of that discussion may result in the start of formal action being taken against them under the relevant trust disciplinary procedure.

18. In cases where the allegation involves an honorary appointee the allegation will be reported to the employing organisation and a joint investigation will take place. It will be generally expected that the employing organisation will take the lead in the investigation.

19. At this stage the Head of R&D Operations/Director R&D will make a decision whether to suspend the research and if it is appropriate to inform the Research Sponsors of the ongoing investigation.

Sanctions

20. As well as sanctions identified within Conduct/Disciplinary Action Procedure and Performance Management Procedure for Medical Staff other sanctions, through the authority of the Director of R&D, may include:

20.1. Withdrawal of formal Confirmation of Capacity and Capability for continuation of the research project and, possibly, any research projects in which the individual concerned has involvement,
20.2. Withdrawal or correction of pending or published abstracts and papers from the research in question,
20.3. Changes in staffing to the project,
20.4. More frequent auditing and closer monitoring of future work,
20.5. Barring the researcher from conducting research in the Trust for a given period,
20.6. Revoking an honorary research contract

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

22. 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.

23. In the case of misconduct related to involvement in Clinical Trials of Investigational Medicinal Products, 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.

Review

24. This policy will be reviewed every 3 years, as set out in the Developing and Managing Policies and Procedural Documents Policy.

References

25. The Medicines for Human Use (Clinical Trials) Regulations 2004 and Amendments

26. UK Policy Framework for Health and Social Care (2017)

Appendix 1: Responsibilities

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

2. The **Chief Medical Officer / 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) (Amended) Regulations 2013

3. The **Director of Research & Development** has delegated authority and is responsible for working with the Head of R&D Operations / Head of R&D Governance to ensure that all concerns are addressed in an appropriate manner.

4. The **Head of R&D Operations / Head of R&D Governance** is responsible for receipt of concerns with regard to possible research misconduct and for ensuring that such concerns are investigated and followed up to a successful conclusion.

5. All **employees of the Trust** including those with honorary contracts have a responsibility to report any incident of misconduct whether this has been witnessed or suspected.

6. All **medical employees of the Trust including those with honorary contracts** are expected to work with the Divisional Director, in order to declare, in their annual medical appraisal, their extent of participation in research activities. This should include the governance of those studies, compliance with any required training such as Good Clinical Practice, and any serious incidents and / or complaints in relation to their research activities, in accordance with the requirements of Medical Revalidation as outlined by the GMC.

Appendix 2: Definitions

1. **Misconduct in research** or **misconduct** for the purpose of this policy means the fabrication, falsification, plagiarism, or deception in proposing, implementing or reporting results of research and deliberate, dangerous or negligent deviations from accepted practice in implementing research.
2. It includes failure to follow an agreed protocol if this failure results in unreasonable risk or harm to humans or the environment and facilitating misconduct in research by collusion in, or concealment of, such actions by others. It also includes any plan or conspiracy or attempt to do any of these things. In addition, it includes intentional unauthorised use, disclosure of or removal of or damage to research related property of another, including apparatus, materials, writings or devices used or produced by the conduct of research.
3. It also includes undertaking a research project, without the appropriate permissions.
4. It does not include honest error or honest differences in interpretation or judgment in evaluating research methods or results, or misconduct unrelated to research processes.

Appendix 3: Education and Training

1. Attention will be drawn to this policy within mandatory training in Good Clinical Practice.
2. Training required to fulfil this policy will be provided in accordance with the Trust's Training Needs Analysis. Management and monitoring of training will be in accordance with the Trust's Core Skills Policy. This information can be accessed via the Practice Development and Education pages on the Trust intranet.

Appendix 4: Monitoring Compliance

3. Compliance with the document will be monitored in the following ways.

What is being monitored:	How is it monitored:	By who, and when:	Minimum standard	Reporting to:
Reports received and resolved	Review of report log. Reporting of generic issues	Head of R&D Governance	Ongoing	R&D Committee
Declaration of research activities and involvement in complaints and incidents included in annual medical appraisal	Completion of pro forma by R&D office with extracts from relevant databases for each doctor due to revalidate in a given time period	Chief Medical Officer's Office for the Responsible Officer	Monthly	N/A

Appendix 5: Equality Impact Assessment

Equality Impact Assessment Template

1. As part of its development, this policy and its impact on equality has been reviewed. The purpose of the analysis is to minimise and if possible, remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation or religious belief.

What is being assessed	Existing Policy
Job title of staff member completing assessment	Head of R&D Governance Shahista Hussain
Name of policy / service / function:	Integrity in Clinical Research Policy & Procedure
Details about the policy / service / function	Policy detailing the procedure for reporting and handling misconduct.
Is this document compliant with the Web Content Accessibility Guidelines?	Yes
Review Date	July 2027
Date assessment completed	July 2024
Signature of staff member completing assessment	Shahista Hussain
Signature of staff member approving assessment	Shahista Hussain

2. Screening Stage

Who benefits from this policy, service or function? Who is the target audience?

- Patients
- Staff
- Others (commercial and non commercial sponsors for hosted studies)

Does the policy, service or function involve direct engagement with the target audience?

Yes - *continue with full equality impact assessment*

3. Research Stage

Impact Assessment

Characteristic	Positive Impact	Negative Impact	Neutral Impact	Not enough information	Reasoning
Sex and Gender Re-assignment – men (including trans men), women (including trans women) and non-binary people.			X		All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researcher as appropriate.
Race - Asian or Asian British; Black or Black British; Mixed Race; White British; White Other; and Other			X		All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researcher as appropriate.
Disability - disabled people and carers			X		All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researcher as appropriate.
Age			X		All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researcher as appropriate.
Sexual Orientation			X		All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researcher as appropriate.
Religion or Belief			X		All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researcher as appropriate.
Pregnancy and Maternity			X		All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researcher as appropriate.
Marriage or Civil Partnership			X		All complaints or allegations are judged on individual merit considering any and all relevant

Characteristic	Positive Impact	Negative Impact	Neutral Impact	Not enough information	Reasoning
					individual requirements of each trial/patient/researcher as appropriate.
Other Groups / Characteristics - for example, homeless people, sex workers, rural isolation.			X		All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researcher as appropriate.

Sources of information
None

Consultation with protected groups

Group	Summary of consultation
None	

Consultation with others
Based on the previous version, update has drawn on feedback from researchers, other staff, complaintees and complainants.

4. Summary stage

Outcome Measures
Implementation of this policy will:

- Enable staff working in research to carry out their roles in accordance with Good Clinical Practice to ensure high standards are maintained.
- Enable staff working in research to report suspected misconduct in research to the appropriate party and for that to be investigated.

These outcomes will be equitably and fairly achieved for all protected groups

Positive Impact
No specific positive impact on protected groups have been identified.

Unjustifiable Adverse Effects
No specific adverse effects on protected groups have been identified

Justifiable Adverse Effects
No specific adverse effects on protected groups have been identified.

Equality Impact Assessment Action Plan

Identified risk	Recommended actions	Lead	Resource implications	Review date	Completion date
None identified	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable