Oxford University Hospitals NHS
NHS Trust

Integrity in Clinical Research Policy & Procedure
Version 3.0

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 Assessment undertaken:	29 September 2017
Valid From:	September 2017
Date of Next Review:	September 2020
Approval Date/ Via:	Trust Management Executive
Distribution:	Trust-wide
Related Documents:	Conduct/Disciplinary Action Procedure Performance Management Procedure for Medical Staff Raising Concerns (Whistleblowing) Policy
Lead Director:	Director of R&D
Author(s):	Head of Research Governance
Further Information:	Head of Research Governance
This Document replaces:	Integrity in Research Policy Version 2.0

Contents

Introduction

1. The Department of Health's Research Governance Framework for Health and Social Care 2005 (RGF) 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.

Policy Statement

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. the Department of Health's Research Governance Framework; 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.

Scope

4. This document 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.

Aim

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

   5.1 The reporting of concerns with regard to the conduct of clinical research with- in the Trust.

   5.2 The investigation of such reports.

Definitions

6. **Misconduct in research** or **misconduct** for the purpose of this policy means the fabrication, falsification, plagiarism or deception in proposing, implementing or re- porting results of research and deliberate, dangerous or negligent deviations from accepted practice in implementing research.

7. 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.

8. It also includes undertaking a research project, without the appropriate permissions.

9. 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.

Responsibilities

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

11. The **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) (Amended) Regulations 2013

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

13. The **Head of Research Governance** is responsible for receipt of concerns with regard to possible re- search misconduct and for ensuring that such concerns are investigated and followed up to a successful conclusion

14. 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.

15. 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.

Content of the Policy

Confidentiality

16. Suspicions reported in confidence and in good faith will not lead to disciplinary proceedings against the person making the complaint and the Trust's Raising Concerns (Whistleblowing) Policy will apply for qualifying disclosures. However, in the event of a malicious allegation, appropriate action will be taken

17. 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.

18. 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

19. 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.

20. Reports of misconduct, either witnessed or suspected should be made to the Head of Research Governance in the first instance.

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

22. 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 Director of R&D.

23. 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.

24. The 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.

25. 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.

26. At this stage the 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

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

    27.1 Withdrawal of formal Trust Management Approval for continuation of the particular research project and, possibly, any research projects in which the individual concerned has involvement,

    27.2 Withdrawal or correction of pending or published abstracts and papers from the research in question,

    27.3 Changes in staffing to the project,

    27.4 More frequent auditing and closer monitoring of future work,

27.5 Barring the researcher from conducting research in the Trust for a given period,

27.6 Revoking an honorary research contract

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

29. 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.

30. In the case of misconduct related to involvement in Clinical Trials of 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.

Training

31. Attention will be drawn to this policy within mandatory training in Good Clinical Practice.

Monitoring Compliance (*This is a mandatory heading for policy documents*)

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

Aspect of compliance or effectiveness being monitored	Monitoring method	Responsibility for monitoring (job title)	Frequency of monitoring	Group or Committee that will review the findings and monitor completion of any resulting action plan
Reports received and resolved	Review of report log. Reporting of generic issues	Head of Research 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	Medical Director's Office for the Responsible Officer	Monthly	N/A

Review

33. This policy will be reviewed in 3 years, as set out in the Policy for the Development and Implementation of Procedural Documents

References

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

35. The Department of Health Research Governance Framework for Health and Social Care 2005

Equality Impact Assessment

36. 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. Please refer to Appendix 12.

List of Appendices

37. The following appendices are attached to support this document:

Appendix 1: Equality Impact Assessment: Full Analysis

Document History

Date of revision	Version number	Reason for review or update
04/06/2014	2.0	General update, incorporating revalidation
29/08/2017`	3.0	General review and update

Appendix 1: Equality Impact Assessment

Equality Analysis
Policy / Plan / Proposal name: Integrity in Clinical Research Policy & Procedure
Date of Policy: September 2017
Date due for review: September 2020
Lead person for policy and equality analysis: Heather House
The only policies and proposals not relevant to equality considerations are those not involving people at all (for example equipment such as fridge temperature)
Identify the main aim and objectives and intended outcomes of the policy Policy detailing the procedure for reporting and handling misconduct.
Involvement of stakeholders Based on the previous version, update has drawn on feedback from researchers, other staff, complaintees and complainants.
Evidence All trials conducted within the Trust have been subject to an R&D review for Trust Management Approval in addition to the appropriate ethical review to ensure that all groups (including any potential patient and all staff) are made aware of the proper complaints procedure and offered adequate and appropriate support.
Disability All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Learning Disability All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Sex All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Age All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Race All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Sexual orientation All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Pregnancy and maternity All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Religion or belief. All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Gender re-assignment All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Marriage or civil partnerships All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Carers All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Safeguarding people who are vulnerable

Equality Analysis
All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Other potential impacts, for example culture, human rights, socio economic, for example homeless people All complaints or allegations are judged on individual merit considering any and all relevant individual requirements of each trial/patient/researchers as appropriate.
Summary of Analysis
Does the evidence show any potential to discriminate? No - the series of reviews (as well as array of legislation) governing each trial ensures all patients are adequately protected and able to proceed any complaints through the proper channels. All staff receive HR training. All complaints are assessed individually.
How does the policy **advance equality of opportunity?** All complaints are taken extremely seriously.
How does the policy **promote good relations between groups** (promoting understanding)? Encourages any and all people involved in a trial to come forward with their concerns to be dealt with in a fair and open manner.