Queen Victoria Hospital
NHS Foundation Trust

Policy on Misconduct and Fraud in Research

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RATIFYING COMMITTEE	Quality and Governance Committee
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DIRECTOR LEAD	Nicky Reeves, Deputy Director of Nursing
AUTHOR	Sarah Dawe, R&D Manager
EQUALITY and HUMAN RIGHTS IMPACT ANALYSIS	121218-2
CONSULTATION	R&D Governance Group, including external scientific advisors from Brighton University, and patient representatives
THIS DOCUMENT REPLACES	Policy on Misconduct and Fraud in Research CP.2014.3
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Document History and Control:

Version	Date Ratified	Brief summary of changes/ amendments	Author/ contributor

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Contents

1. Introduction

General statement of strategy

The Trust will promote high ethical standards for any medical research that is undertaken on its premises or by its employees, and accepts its responsibility for maintaining a robust system of research governance.

This policy will be reviewed at least every three years and in the light of major changes in strategic direction and /or major organisational changes

2. Purpose

To prevent incidences of research misconduct at the Trust.

3. Scope

The 'Trust' is defined as the Queen Victoria Hospital NHS Foundation Trust. 'Employees' is defined as those people who hold either substantive or honorary contracts with the Queen Victoria Hospital NHS Foundation Trust.

'Research misconduct' is defined as:

The fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research, or 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 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.

It does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct unrelated to the research process. Similarly it does not include poor research unless this encompasses the intention to deceive[1].

4. Duties

4.1 The Trust's responsibilities are:

The Queen Victoria Hospital NHS Trust has responsibility for maintaining high ethical standards for any medical research that is undertaken on Trust premises[2]. The Trust is also charged to monitor all research that is ongoing and to investigate promptly and fairly where episodes of misconduct have been alleged. Findings of research misconduct may be matters for consideration under the Trust's disciplinary procedures[3]. Research misconduct is taken seriously and any member of staff raising *bona fide* concerns can do so confidentially, and without fear of suffering any detriment[4]. In line with the Public Interest Disclosure Act 1998, no employee, who makes an allegation in good faith against another employee, shall suffer a detriment.

Contracts of employment for all newly appointed staff outline the need to be aware of and comply with the UK Policy Framework for Health and Social Care Research. Access to R & D policy and procedures regarding research misconduct and the management of research will be via the intranet and R & D Department.

- **Responsibilities of Researchers**

Researchers bear the day-to-day responsibility for the conduct of research. They are responsible for ensuring that any research they undertake follows the agreed protocol, for helping care professionals to ensure that participants receive appropriate care while involved in research, for protecting the integrity and confidentiality of clinical and other records and data generated by the research (including lab-based data), and for reporting any failures in these respects, adverse drug reactions and other events or **suspected misconduct** through the appropriate systems.

- **Responsibilities of the Principal Investigator (P.I.)**

He/She accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs.

- **Responsibilities of Directorates and Departments:**

1. The P.I. will be responsible for the conduct of members of their own departments in conducting research.
2. All new projects must have the support of their Department prior to gaining Trust R&D approval.

3. The P.I. must be satisfied that all junior members of staff undertaking research are properly and adequately supervised.
4. The P.I. must be satisfied that those clinicians or scientists conducting research are capable and have an appropriate level of research expertise to enable good quality research to be undertaken.
5. The P.I. must be alert to the possibility of fraud within their clinical areas.
6. All researchers must communicate with their supervisors, where appropriate, on a regular basis and this must be documented. Supervisors must in turn communicate regularly with the R&D department, and this too must be documented.

- **Responsibilities of Research Workers**

1. Any person undertaking research is required to record their data in a secure and durable format. Electronic data on the Trust's network is backed up by the IT Dept. It is the responsibility of individual researchers to ensure that any other electronic data is backed up.

2. All documentation pertaining to the research project must be kept by the Department in a secure and durable form for the period specified on their Ethics Application.

   All researchers must ensure that the projects have received Trust approval through the R&D Governance Group, as well as Ethical approval (or Health Research Authority Approval). The granting of approval by the Ethics Committee does not mean that the Trust would necessarily approve the study to go forward. Failure to seek Trust approval is in itself tantamount to misconduct.

- **Responsibilities of Clinical Lead for R&D**

1. The Clinical Lead for R&D will be the initial investigator for allegations of research misconduct, and will raise it as appropriate with the Chief Executive, who can authorise an official investigation. The Clinical Lead for R&D and the Chief Executive will take the allegations of research misconduct seriously and will investigate fairly where the allegation appears justified.

2. The Clinical Lead for R&D will ensure that 10% of research projects are audited on a regular basis to ensure that practices are being undertaken correctly.

3. The Clinical Lead for R&D will ensure that a record is kept of all research being undertaken in the Trust.

4.2 Committees and Groups with Overarching Responsibilities

Any incidences which require further investigation will be reported to the R&D Governance Group, and may be logged on Datix, or referred to the Trust Local Counter Fraud Specialist for further investigation if deemed necessary. The R&D Governance Group reports into the Quality & Governance Committee.

5. Authorship

Only those workers who have had direct involvement in the work should be put forward as authors, as agreed by the Vancouver statements[7] .

Investigators should disclose to the Trust and on publication any conflict of interest, such as employment, consultancies, stock ownership or options, honoraria, patents, as described by the ICMJE(10).

6. Procedures for the reporting of concerns

Initial contact should be made via the person's line manager or directly to the Clinical Lead for R&D. The Clinical Lead for R&D will then take the appropriate action, according to the existing Trust policies and procedures for raising issues of concern[5] and investigating clinical incidents[6].

Allegations will be passed on to the Medical Director and other appropriate personnel depending on the nature of the allegation, grade and profession of person under investigation. The existing Trust procedures for investigation and disciplinary action[8] will be followed. Where necessary, legal advice will be sought via the Trust Medico-Legal Department.

The Clinical Lead for R&D will ensure that the appropriate funders and/or sponsors of the research project are notified at the earliest opportunity about allegations of serious research misconduct. In the case of animal research, the Home Office will be notified as soon as a concern has been raised. The Trust is also responsible for informing sponsors of the outcome of any such investigation.

Registered Medical Practitioners who are found to have committed serious research misconduct will be reported to the General Medical Council under its Fitness to Practice Procedures[9]. Any other healthcare professionals will be referred to their relevant bodies.

7. Training and Awareness

This policy will be made available on the Trust internet. All staff will be shown where policies are as part of their local induction on the Trusts internet.

8. Equality

This policy and protocol has been equality impact assessed in accordance with the Trust's impact assessment toolkit. Completed assessments are available upon request from qvh.eqia@nhs.net.

The Trust recognises the diversity of the local community and those in its employ. Our aim is, therefore, to provide a safe environment free from discrimination and a place where all individuals are treated fairly, with dignity and appropriately to their need. The Trust recognises that equality impacts on all aspects of its day to day operations and has produced an Equality Policy Scheme to reflect this. All policies and procedures are assessed in accordance with the equality impact assessment tool, the results of which are monitored by the Equality and Diversity Group.

9. Data Protection

The Data Protection Act 2018 protects personal data which includes information about staff, patients and carers. The NHS relies on maintaining the confidentiality and integrity of its data to maintain the trust of the community. Unlawful or unfair processing of personal data may result in the Trust being in breach of its data protection obligations.

10. Freedom of Information

Any information that belongs to the Trust may be subject to disclosure under the Freedom of Information Act 2000. This Act allows anyone, anywhere to ask for information held by the Trust to be disclosed (subject to limited exemptions). Further information is available in the Freedom of Information Act Trust Procedure which can be viewed on the Trust Intranet.

11. Records Management

Records are created or received in the conduct of the business activities of the Trust and provide evidence and information about these activities. All records are also corporate assets as they hold the corporate knowledge about the Trust. The Trust has a Records Management Policy for dealing with records management. Compliance with and the application of this policy will ensure that the Trust's records are complete, accurate and provide evidence of and information about the Trust's activities for as long as is required.

12. Review

This policy will be reviewed in 3 years' time. Earlier review may be required in response to exceptional circumstances, organisational change or relevant changes in legislation or guidance.

13. Discipline

Breaches of this policy will be investigated and may result in the matter being treated as a disciplinary offence under the Trust's disciplinary procedure.

14. Monitoring Compliance with this Policy

Activity being monitored	Methodology to be used for monitoring	Responsibility for monitoring	Frequency of monitoring and reporting	Process for review and improvement
Instance of research fraud	Fraud will be reported to Clinical Lead for R&D and the Trusts Local Counter Fraud Specialist	Clinical Lead for R&D	As instances arise	Via R&D Governance Group in the first instance

15. References

1. General Medical Council, *Good Practice in Medical Research*, Jan 2008, www.gmc-uk.org
2. UK Policy Framework for Health and Social Care (v3.3 - November2017), www.hra.nhs.uk
3. QVH Disciplinary Policy and Procedure, (contact Human Resources)
4. QVH Raising Concerns (Whistle blowing) Policy, (contact Human Resources)
5. QVH Raising Concerns (Whistle blowing) Policy, (contact Human Resources)
6. QVH Counter Fraud Policy
7. The International Committee of Medical Journal Editors of over 400 journals (the 'Vancouver Group') *New England Journal of Medicine* (1991:324; 424428)
8. QVH Disciplinary Policy and Procedure, (contact Human Resources)
9. General Medical Council, Fitness to Practice, www.gmc-uk.org
10. See,http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html

Bibliography

F.O.Wells. *Clinical Research Fraud and Misconduct: How is it diagnosed?*

The COPE Report, 2000

Kalb, Paul E. MD, JD; Koehler, Kristin Graham JD. Legal Issues in Scientific Research. *JAMA*, Vol 287 (1). Jan 2, 2002; 85-91.

R. Smith. *What is Research Misconduct?* The COPE Report, 2000.