# Research Fraud and Misconduct

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1. PURPOSE

This Standard Operating Procedure (SOP) details what healthcare research (scientific) misconduct is and the procedure for dealing with allegations of research fraud or misconduct.

This SOP has been produced in accordance with ICH GCP, the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and The Research Governance Framework for Health and Social Care (RGF) 2005, and covers local procedures for investigating and responding to allegations of Research Misconduct & Fraud.

2. INTRODUCTION

This SOP is for both Imperial College Healthcare Trust (ICHT) employees and Imperial College London (ICL) employees.

ICL employees should also refer to Ordinance D17 – Investigation of Allegations of Research Misconduct and ICHT employees should also refer to the Raising Concerns Policy and Procedure (Whistle blowing).

For the purposes of this SOP the definition of scientific misconduct is taken from the Medical Research Council Misconduct Policy and Procedure (December 2008).

“Scientific misconduct means 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 misconduct in research by collusion in, concealment or 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.”

All ICL and ICHT staff, including those holding honorary contracts have a duty to report any incident of misconduct, whether this has been witnessed or whether it is suspected in respect of clinical research conduct and management.

2. 1 Principles of Reporting Suspected Research Misconduct or Fraud

ICL and ICHT expect researchers to be aware of the Research Governance Framework, Joint Research Compliance Office Standard Operating Procedures, ICH GCP Guidelines, and the regulations that pertain to their research management and conduct.

The process for reporting allegations enables individuals to raise concerns relating to research misconduct and makes it clear to individuals who believe they need to make an allegation against a member of staff that this will be taken seriously.
• Provides a process for concerns to be raised, investigated and, where appropriate, acted upon in a fair and transparent manner and in confidence.

• Provides the opportunity for an individual who has inadvertently breached good practice to declare the problem openly, allowing the process to occur in a fair and transparent manner.

• Acts as a deterrent to potential perpetrators of research misconduct.

• Strengthens the confidence of all research stakeholders that ICHT and ICL maintain the highest standards of research conduct.

3. PROCEDURE

3.1 Investigation

The Research Governance Manager, Clinical Trial Manager and/or Head of Regulatory Compliance of the Joint Research Compliance Office (JRCO) may request a written complaint and will confirm receipt in this instance.

The Head of Regulatory Compliance will commit to investigate the claim within 30 working days and during this time will inform the Respondent of the allegation offering a right of reply.

A communication procedure is in place to ensure key internal parties have knowledge of allegations and investigations, and that the procedure is conducted in a transparent manner. The standard communication process is:

1. Head of Regulatory Compliance notifies the Director and Programme Director of Research
2. Head of Regulatory Compliance notifies HoDs, Divisional Administrators, Trust Divisional Research Directors and Managers, Designated Individual for the HTA Tissue Licence, as applicable.
3. Service and department leads may also be notified if an allegation is deemed to impact on their service

The Head of Regulatory Compliance may decide to delegate the investigative process if appropriate.

• The delegated individual will decide how an investigation should take place and what form it should take
• The delegated individual will appoint relevant person/s to investigate the allegation
• In the event of financial implications, the Assistant Director of Finance / Head of Post Award should be informed
• Inform employers of those individuals holding honorary contracts, of the Investigation
• The outcome of an investigation will be reported to the Head of Regulatory Compliance who will decide whether there are grounds for proceeding further
3.2 Outcome of Investigation

If a serious allegation of fraud is made and is supported by credible evidence, then ICHT or ICL has a duty to report this to the NHS Counter Fraud Service who will advise in deciding how the investigation should proceed. In some cases this may include the involvement of the Police.

Where the individual holds an honorary contract, the individual’s employer will be informed of the intention to pursue an investigation. It will be the responsibility of the substantive employer of these staff to undertake any further disciplinary action. The Joint Research Compliance Office will, where appropriate, also report to Regulatory and approval Bodies (such as MHRA, HTA, HRA, NRES, GMC).

The process of the investigation will be recorded in the Research Misconduct and Fraud action log filed in the Trial Master File and within the Joint Research Compliance Office.

The JRCO will also notify any instances of Research Misconduct and Fraud to the study’s Sponsor.

If the study is a multicentre study, the JRCO may notify all sites if evidence or suspicion of misconduct or fraud.

Reports on the investigation and subsequent outcomes may be submitted to College and/or Trust committees for review and comment, as applicable.

If there is funding attached, from commercial or non-commercial organisations, the JRCO may notify the funder depending on the contractual arrangements in place.

Cases raised on the basis of genuine concern about the legitimacy of research will not result in disciplinary action against the complainant.

Should an allegation be not proven and is of a frivolous, mischievous or malicious nature, the findings are to be reported to the Director of HR, for action under normal disciplinary procedures.

4. REFERENCES

Imperial College London Ordinance D17 – Investigation of Allegations of Research Misconduct.

Medical Research Council Misconduct Policy and Procedure (December 2008).

Raising Concerns Policy and Procedure (Whistle blowing). (Imperial College Healthcare NHS Trust version 2, date ratified 13 June 2011)

Department of Health (DoH) Research Governance Framework for Health & Social Care, 2nd Edition, April 2005

*Guidelines for Good Clinical Practice (GCP) (E6 R1 Step 4, 1996)*

**2006 No. 1928 MEDICINES**
The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006