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Research Fraud and Misconduct

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Version	Date	Reason for Change
Version 1.0	05 Sep 2011	New SOP
Version 2.0	03 Dec 2012	Annual review
Version 3.0	18 Feb 2015	Scheduled review
Version 4.0	18 Aug 2017	Scheduled review
Version 5.0	19 Oct 2020	Scheduled review Templates removed and administrative changes to SOP. JRCO name change to RGIT

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

This SOP has been produced in accordance with the International Conference on Harmonisation of Good Clinical Practice (ICH GCP), the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and the Research Governance Framework for Health and Social Care (RGF) 2005. It covers local procedures for investigating and responding to allegations of research misconduct and fraud.

2. INTRODUCTION

Producing high quality and ethical research depends on the integrity, honesty and professionalism of all individuals involved in the research process. Research organisations' staff recruitment practices at all levels should reflect the importance of these qualities.

ICL employees must 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's Good research practice: Principles and guidelines (July 2012).

Research misconduct is defined by the Medical Research Council and Research Councils UK as follows:

- Fabrication
- Falsification
- Plagiarism
- Misrepresentation
- Mismanagement or inadequate preservation of data and/or related materials
- Breach of duty of care"

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.

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 and 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.

The process for reporting allegations further:

- 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**

Within the Research Governance and Integrity Team (RGIT), the Research Governance Manager, Clinical Trial Manager and/or Head of Research Governance and Integrity may request a written complaint and will confirm receipt in this instance.

Where the complaint relates to a solely Imperial College allegation, the Head of Research Governance and Integrity will escalate the issue to the College Secretary for assessment and investigation in line with College Policy and follow the Ordinance D17 procedure.

For all other allegations, the Head of Research Governance and Integrity will investigate the claim and 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 Research Governance and Integrity notifies the Director and Programme Director of Research
2. Head of Research Governance and Integrity notifies Heads of Departments, 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 Research Governance and Integrity 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 Research Governance and Integrity 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 RGIT 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 within the RGIT.

The RGIT will also notify any instances of research misconduct and fraud to the study's sponsor.

If the study is a multicentre study, the RGIT may notify all sites of 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 RGIT 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 found to be 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 Good research practice: Principles and guidelines
- Department of Health (DoH) UK Policy Framework for Health & Social Care Research
- Guidelines for good clinical practice E6(R2) Step 5
- The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006