St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

SOP ID number:	JREOSOP0025	**Effective Date:**	02/11/2015
Version number and date:	Version 2.0 30/10/2015	**Review Date:**	02/11/2017
Author:	Anika Kadchha	**Title:**	Research Governance Officer
Approved by:	Lucy H H Parker	**Date:**	30/10/2015
Signature of Authorisor			

This is a controlled document.
The master document is posted on the JREO website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JREO website for the most recent version.
They may print off this document for training and reference purposes.

Standard Operating Procedure (SOP)
Research Misconduct or Fraud

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
v1.0	New SOP	Lucy H H Parker
V2.0	Updated Logo and Trust Name	Anika Kadchha

© St George's

Table of Contents	Page
1. Background	3
2. Joint Research and Enterprise Office (JREO) Policy	3
3. Scope	3
4. Definitions 4.1 Research Misconduct	4 4
5. Responsibilities	4
6. Procedures	4
7. References	5
8. Appendices n/a	5

© St George's

1. Background

SGUL and SGHT expect researchers to be aware of the Research Governance Framework, the JREO SOPs, 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 purposes of this procedure are:

a. To enable individuals to raise legitimate concerns relating to research misconduct.

b. To provide a process for concerns to be raised, investigated and, where appropriate, acted upon in a fair and transparent manner and in confidence.

c. To make clear to individuals who believe they need to make an allegation against a member of staff that such an allegation will be treated seriously and in accordance with this Policy and the Public Interest Disclosure (Whistleblowing) Policy and procedure.

d. To deter research misconduct.

e. To provide a degree of public confidence that the Trust and the University maintain the highest standards of research conduct.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JREO acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent both institutions acting as Sponsor.

3. Scope

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

© St George's

This SOP has been produced in accordance with ICH GCP, the Medicines for Human

Use (Clinical Trials) Regulations (2004) and subsequent amendments, The Research Governance Framework and refers to local policies for investigating and responding to allegations of Research Misconduct & Fraud.

4. Definitions

4.1 Research Misconduct

For the purposes of this SOP, the definition of research misconduct is taken from the Wellcome Trust's definition,

"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, data, hardware or software or any other substances 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"

5. Responsibilities

All SGUL and SGHT 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.

6. Procedure

SGUL employees should refer to and follow the policy on Research Misconduct – https://portal.sgul.ac.uk/org/cs/hr/A-Z policies-and-procedures/Research Misconduct Procedure 2012_FINAL.pdf

© St George's

SGHT employees should refer to and follow the policy on Research Misconduct

St George's University Hospitals NHS Foundation Trust (SGHT) Research Misconduct policy
http://stginet/Procedural%20Documents/Corporate%20-%20IT/Governance/Org_4_2.doc

7. References

The Wellcome Trust's statement on research misconduct (2002 – updated 2005)

www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002756.htm

St George's University Hospitals NHS Foundation Trust (SGHT) Research Misconduct policy
http://stginet/Procedural%20Documents/Corporate%20-%20IT/Governance/Org_4_2.doc

St George's, University of London Research Misconduct policy

https://portal.sgul.ac.uk/org/cs/hr/A-Z policies-and-procedures/Research Misconduct Procedure 2012_FINAL.pdf

Research Governance Framework for Health & Social Care, 2nd Edition, April 2005
www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition

The Medicines for Human Use (Clinical Trials) regulations 2004 and as amended

www.legislation.gov.uk/uksi/2004/1031/contents/made

Public Interest Disclosure Act 1998

8. Appendices

Not applicable to this SOP

© St George's