Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Breach of Patient Confidentiality in IMP Studies**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	20/10/11	Annual Review	Final v 2.0
Final v 2.0	21/08/2012	Periodic Review	Final v 3.0
Final v 3.0	06/10/2014	Periodic Review	Final v 4.0
Final v 4.0	19/12/2016	Periodic Review	Final v 5.0

1. Purpose

This Standard Operating Procedure (SOP) provides guidance to researchers, especially those in laboratory facilities, in the event of patient identifiable information being received on University premises.

2. Introduction

The Medicines for Human Use (Clinical Trials) Regulations 2004, incorporating Good Clinical Practice, states that "All Clinical Information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected" (Schedule 1, Part 2, 9) and that "the rights of each patient to physical and mental integrity, to privacy and to the protection of data concerning him in accordance with the Data Protection Act 1998 are safeguarded" (Schedule 1, Part 2, 13).

Unfortunately, by the very nature of clinical trial work episodes occur whereby patient information is inadvertently passed onto University premises.

All samples and documentation received onto University premises should contain an anonymised study identification code and not personal information, unless the study information sheet and consent form explicitly state that the information may be on University premises.

3. Scope

This SOP applies to all studies using Investigational Medicinal Products (IMP) recruiting patients from Health and Social Care Trusts.

4. Responsibilities

4.1 Chief Investigator/Site Principal Investigator (PI)

The Chief Investigator (CI)/Site Principal Investigator (SPI) must ensure that all those involved in the research study understand that it is a legislative breach to have patient identifiable information on University premises, without the explicit and informed consent of the patient. In the event of a confidentiality breach, the CI/SPI must contact the source of the patient information highlighting the issue and determining appropriate corrective actions to prevent a repeated incident.

4.2 Investigator/Laboratory Technician

All those involved in a research study have the responsibility to preserve patient confidentiality. In the event of documentation and/or clinical specimens being received into the University containing patient identifiable information corrective action must be taken and the CI/SPI informed.

5. Procedure

5.1 The individual who receives the document or sample with patient identifiable information must report the incident immediately to the CI/SPI and the person sending the samples. Detail the information that has been received into the University and obtain an anonymised study identification code for the particular research subject. In the event that the study co-ordinator is not available assign a unique identification code.

5.2 Record the patient details and any assigned study codes carefully on the "breach of confidentiality" form, attached as Appendix 1 and retain securely until collected by the study co-ordinator. The form must be retained in the Trial Master File.

5.3 In event of a document being received with patient identifiers on it, these should be redacted by blanking out the patient details and photocopying of the page. Once the photocopy is checked for completeness, the original document must be shredded and disposed of in confidential waste.

5.4 In the event of a specimen being received, the specimen container must be re-labelled with the allocated anonymised study identification code. Care must be taken to obliterate the patients' details.

5.5 In the event that the receiver has had to assign their own unique number to documentation or a specimen, ensure that once the correct study number has been obtained that everything is updated.

5.6 Process the documentation and/or sample as required by the study protocol and report the incident to the Chief Investigator.

6. References

Medicines for Human Use (Clinical Trials) Regulations 2004 (last accessed December 2016) http://www.legislation.gov.uk/uksi/2004/1031/contents/made
Centre for Public Health. Incident Reporting Protocol

7. Appendix

Appendix 1 – Breach of Confidentiality Form.

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Breach of Patient Confidentiality

Study Title: _____

Chief Investigator: _____

Breach that occurred: Specimen received ☐ Documentation received ☐

Name of patient _____

Address _____

DOB _____

Consultant _____

Anonymised Study Identification Code (as given by study co-ordinator)_____

Unique study code (given by receiver)_____

Signed (receive of data)_____