Standard Operating Procedure
Research Governance

Title:	Breach of Participant Confidentiality in Research Studies		
SOP Reference Number:	QUB-RGEI-021	Version Number:	FINAL v 1.0
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) describes the process to be followed by researchers in the event of personal identifiable information being received on University premises, where this receipt has not been explicitly addressed in the study Information Sheet and Consent Form. It also describes the process to follow if personal identifiable information is transferred from the University to another organisation, where this transfer has not been explicitly addressed in the study Information Sheet and Consent Form.

Both these situations would be classed as a data breach and require immediate reporting.

2. Procedure

2.1 Data Breach from QUB to another organisation or internally within QUB

Where the data breach originated from the University, then the University's Data Breach Policy must be followed. Details of this can be found at: https://www.qub.ac.uk/about/Leadership-and-structure/Registrars-Office/Information-Compliance-Unit/Data-Protection/report-data-breach/. Relevant forms can also be sourced here. In the context of a research study, the Chief Investigator is the individual who should report the incident to the data breach inbox (databreach@qub.ac.uk). Where the breach is identified by a member of the research team, that person must report the breach immediately to the Chief Investigator for onward reporting.

If the University is the sponsor for the research, then the Research Governance, Ethics and Integrity team should also be notified of the breach (researchgovernance@qub.ac.uk).

2.2 Data Breach from external organisation to QUB

Where the data breach originated from outside the University the senior member of the research team in the University should report the breach to the study sponsor, who will be responsible for identifying the Data Controller for the study and the relevant procedure to follow.

2.3 Redacting documentation/sample

If in receipt of a document containing personal identifiable information, where consent for this has not been given, these data should be returned to the sender for redaction. If the document was received via email, once returned the original email and the returned email should be deleted. The data breach should be reported as per 2.2.

If a sample is received with participant identifiers, the sample must be relabelled with the allocated anonymised study identification code. Care must be taken to obliterate the participant details. If it is not possible to obtain the anonymised study ID code, a temporary unique identifier should be assigned. The data breach should be reported as per 2.2.

If it has been necessary to assign a temporary unique identifier, ensure that everything is updated once the correct study number has been obtained.

You should then process the documentation and/or sample as per the study protocol.

3. References

QUB Data Breach Policy and Forms: https://www.qub.ac.uk/about/Leadership-and-structure/Registrars-Office/Information-Compliance-Unit/Data-Protection/report-data-breach/

QUB Data Protection Policy: https://www.qub.ac.uk/about/Leadership-and-structure/Registrars-Office/Information-Compliance-Unit/Data-Protection/data-protection-policy/

QUB Research Data Protection Guidance: https://www.qub.ac.uk/about/Leadership-and-structure/Registrars-Office/FileStore/Filetoupload,945308,en.pdf

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