


Standard Operating Procedures (SOP) for:			
Data Protection for Research Projects			
SOP Number:	16	Version Number:	5.0
Effective Date:	06/12/2014	Review Date: Reissue review date:	06/12/2016 06/12/2017

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Authorisation:	
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Signature	
Date	20/12/2013

Purpose and Objective:
To ensure the research project complies with the Data Protection Act, 1998, Caldicott guidelines 1997, and the NHS Confidentiality Code of Practice. To advise investigators how to maintain patient and staff confidentiality whilst conducting the research project.
Scope:
This SOP applies to all research projects submitted to the JRMO for review for R&D approvals. For DPA input for proportionate review please see relevant SOP.

SOP Text

	Responsibility	Activity
1.	Principal Investigator (PI) and research teams	Contact the Information Governance department for advice on any Information Governance, Data Protection and Caldicott issues which arise during the ethical submission of a research project; or to receive advice on projects requiring NIGB approval.

2.	Research Ethics Facilitator / Information Governance	<p>Check that the information within the IRAS form, information sheets and consent forms is consistent with Data Protection Act and local policy requirements.</p> <p>Items for scrutiny:</p> <ul style="list-style-type: none"> • Recruitment and consent process • Confidentiality measures • Storage and use of data after the end of the study • Transport of data outside of the EU • Data Storage (information asset) • Data Flow mapping • Encryption of portable devices <p>Advise investigators on changes to be made to the documentation or procedures in order to comply with the Trust's policy with regard to data protection, confidentiality and Caldicott requirements.</p> <p>Suggest that current templates on the IRAS and R&D websites are used when appropriate</p>
3.	Research Ethics Facilitator/Information Governance	Complete the Research Data Protection Checklist and when satisfied that the project meets Data Protection Act requirements and Trust Information Governance criteria sign off checklist.
4.	Research Ethics Facilitator	Save a copy of the checklist into ReDA II project files and file the original with the project file in line with the JRMO filing SOP.

Change Control

This section outlines the changes from version 4.0 to version 5.0 of this SOP.

Summary and description of change
<ol style="list-style-type: none"> 1. Correction as the DPA was referenced (in error) as 2003 and not 1998 (typographical error). 2. Section 4 clarification that a copy of the checklist is to be saved into ReDA (and not as an event).

Associated Documents

Document 1	Research Data Protection Checklist
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