HIC SERVICES STANDARD OPERATING PROCEDURE

For the Preparation, Approval and Review of HIC ISMS Documents

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DOCUMENT SECURITY LEVEL:	Open
REVIEW DATE:	This SOP will be reviewed at least every 12 months, or at other times as requested by: HIC Information Governance Committee
AUTHOR:	Duncan Heather
DATE APPROVED BY THE HIC INFORMATION GOVERNANCE COMMITTEE	25th June 2020
DATE APPROVED BY THE HIC EXECUTIVE COMMITTEE:	12th May 2020
DATE REVIEWED BY THE OPS COMMITTEE:	4th May 2020
CONTACT PERSON FOR THIS SOP:	HIC Governance Manager

Document Review and Revision History

Version Number:	Edited by (job title):	Effective Date:	Details of editions made:
1.0	Duncan Heather (HIC Governance Manager)	01/07/15	New SOP
2.0	Duncan Heather (HIC Governance Manager)	01/01/16	Added detail to 5.2 Reviewing and Revising SOPs
3.0	Chris Hall (Senior Data Analyst)	01/04/16	Added reference to Service Descriptions and altered review process.
4.0	Duncan Heather (HIC Governance Manager)	01/10/16	Reduced documents for approval by HIC Governance Committee to "Policy" and "SOPS". Renamed "Governance Documents" as "ISMS Documents"
5.0	Duncan Heather (HIC Governance Manager)	26/02/2019	Added section 5.2.7: staff to read new and changes to existing ISMS docs and for this to be recorded
6.0	Jenn Johnson (HIC Admin)	25/06/2020	Updated Chair, removed physical signature, revised Date Approved to include by X Committee, updated 5.2.1 with new review schedule, update 5.2.2. with approval date

Draft and Archived/Obsolete revisions are not to be used.
Access current versioning system to verify revision.

1. PURPOSE

Health Informatics Centre Services (HIC Services) is a University Research Support Unit operating within the Tayside Medical Science Centre (TASC) at the University of Dundee, in collaboration with NHS Tayside and NHS Fife. HIC Services provides Data Users with linked, anonymised information derived mostly from large Population Based Health Datasets, owned mainly by the NHS and the University of Dundee. HIC also develops data collection software, provides data entry and securely hosts data for research use.

HIC Services maintains a set of documents as part of its Information Security Management System (ISMS). These describe how data is managed and working processes are followed to reduce errors and maximise data security, confidentiality and the quality of HIC's products and services.

The processes followed to consistently create, approve and review ISMS Documents are described in this SOP, with the purpose of creating consistent, high quality documents.

2. SCOPE

This SOP covers the use of standard document templates to create a new ISMS Document; the collaboration of a SOP Development Group; how different ISMS Documents are approved; stored and shared; how follow-up is carried out to review and improve existing versions.

3. DEFINITIONS

For overall Definitions see HIC Services SOP Appendix B – Definitions.

- <u>Standard Operating Procedure (SOP)</u> - Standard Operating Procedures are the top tier giving a clear overview of the routine activity area, without all the operational detail. These are shared more widely and don't hold confidential information.
- <u>Procedure</u> - Procedures (second-tier) describe the process. They are more detailed and often contain both a narrative (i.e. text description of the steps) and visuals, usually in the form of use cases and workflow diagrams.
- <u>Work Instruction (WI)</u> – The third tier provides the lowest level of detail, giving instructions to perform a specific piece of work. Some are less than one page, with just a list of bullet points.
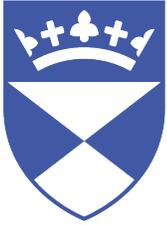
- Service Description (SD) – Another third-tier document specific to IT Infrastructure, in relation to describing technical controls, which contains the level of detail expected in a third tier document, but are closer to second tier in terms of narrative
- ISMS Document – A term to capture all Policies, SOPs, Procedures, WIs, SDs etc. that form part of HIC's overall Information Security Management System document set.
- Technical Lead - head of team (e.g. DLS, ADP, Infrastructure Team) or anyone nominated by the HIC Director for a particular area of documentation.
- Working Documents – Technical documents approved by the relevant / appointed Technical Lead.
- Static and Formally Approved Documents – documents which are reviewed and approved by the HIC Executive and Information Governance Committees as appropriate for the document type.
- SOP Development Group – a collaboration of persons qualified and experienced with the process being documented who are able to ensure the best practice is described accurately.

4. RESPONSIBILITIES

- HIC Director – Responsible for overall HIC security policy, development of appropriate SOPS and implementation. Assigning Technical Leads.
- Governance Manager – Leading on the development of SOPs relating to data security and confidentiality. Monitoring compliance, handling significant events, leading review process.
- Process Manager – Leading on the development and review of Procedures and WIs relating to their process activities, ensuring SOPs, procedures and WIs are followed by team.
- All HIC Staff – to follow procedure when involved in developing SOPs.
- Technical Leads –Responsible for approving any new or edited third tier documents (WIs and SDs) for their relevant area of work.

5. POLICY

For overall Policy see HIC Services SOP Appendix A – Policy.

5.1 Creating a new SOP, Procedure or Work Instruction

5.1.1   Document types and approving bodies; ISMS Documents are classified and approved as follows:

Document Category	Document Type	HIC Exec	HIC Info Gov	Tech Lead
Policies	Static & Formally Approved	Approval	Approval	
SOPs	Static & Formally Approved	Approval	Approval	
Procedures	Static & Formally Approved	Approval		
SDs	Working Document	Info Only		Approval
Work Instructions	Working Document	Info Only		Approval
Asset and Responsibility Matrix	Working Document	Info Only		Approval
Disaster Recovery Plans	Working Document	Info Only		Approval
IT Monitoring Documents	Working Document	Info Only		Approval
IT Diagrams	Working Document	Info Only		Approval
All Other ISMS Docs	Static & Formally Approved	Approval		
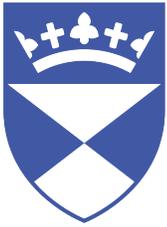
5.1.2   Summary Diagram:
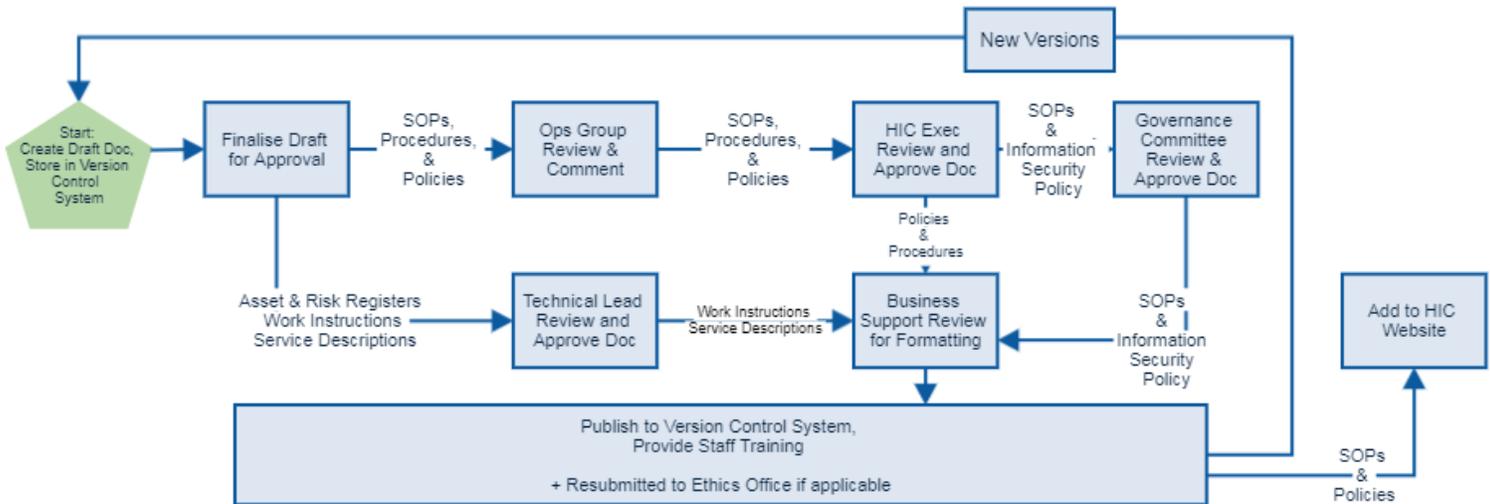
5.1.3   An ISMS Document will be written as soon as the need for one has been identified and no existing ISMS Document is considered suitable. An individual, usually the HIC Governance Manager for Static and Formally Approved Documents or Technical Lead / Process Manager for Working Documents, who is recognised as being appropriately qualified and experienced to carry out this task, will be nominated by the HIC Director to lead the development of the new document.

5.1.4   This will be carried out in consultation with a SOP development group to ensure the best practice is described accurately, with reference to any previous lessons learnt, particularly from Significant Events.

5.1.5   Standard HIC Services ISMS Document templates, stored in HIC Services' versioning and revision control system, will be used to create HIC Services' ISMS Documents.

5.1.5.1   Documents will contain:

1. Document title.
2. Version.
3. Author.
4. Approver.
5. Effective date.
6. Review frequency.
7. Version history.
8. Review history.
9. References.
10. Information classification – where they are unmarked, documents will be considered "open".
11. Organisation name and logo.

5.1.6   All new document drafts will be reviewed and approved as per the Document types and approving bodies table in section 5.1.1.

5.1.7   HIC Services Policies and SOPs will be published on the HIC website.

5.1.8   All HIC ISMS Documents will be stored in HIC Services versioning and revision control system, which will provide an audit trail of all ongoing versions.

5.1.9   Hard copy versions of ISMS Documents are 'uncontrolled' and must not be assumed to be current. All hard copies should be checked against the current electronic version within the HIC document versioning system prior to use and destroyed promptly thereafter, to help ensure current versions are being used.

5.2 Reviewing, Revising and Approving SOPs

5.2.1 HIC ISMS Documents will be reviewed at least annually to ensure they still reflect current best practice, including any process improvement updates identified from Significant Events. An ongoing audit log will be kept of ISMS Documents reviewed, with only updated ISMS Documents being sent for approval as per their document type.

5.2.2 ISMS Documents will remain valid until replaced by a new revised version, with a new version number, effective start date and where applicable an approval date.

5.2.3 Modifications to Static & Formally Approved Documents will be reviewed and approved by the HIC Executive Committee before being sent to the HIC Information Governance Committee for final review and approval.

5.2.4 Modifications to Working Documents will be reviewed and approved by the appointed Technical Lead. A summary of the modifications applied to these will be provided to the HIC Executive Committee for information.

5.2.5 Modifications will be tracked between versions and made available to reviewers to ensure changes are visible.

5.2.6 Any amendments to ISMS Documents that have been previously submitted to the Research Ethics Committee (REC) as part of HIC's "Health Informatics Centre-managed Datasets" favourable ethical opinion will be submitted to the REC for their information.

5.2.7 Any new ISMS Documents or amendments to ISMS Documents, once approved, will be shared with relevant staff for required reading. A record will be kept of staff completing this action.

6. APPLICABLE REFERENCES

- HIC Services SOP Appendix A – Policy
- HIC Services SOP Appendix B – Definitions
- HIC Services SOP Appendix C – Roles and Contact Details
- HIC Staff Handbook