Health Informatics Centre
University of Dundee

bsi ISO/IEC 27001 Information Security Management CERTIFIED
IS 802159

bsi UKAS MANAGEMENT SYSTEMS 0003
IS 802159

Data Access Approvals

PURPOSE

This SOP describes what procedures Approved Data Users need to follow and approvals that are required to enable access to Data provided by HIC Services, including:

- HIC Services Data access approval process
- Providing identifiable data for the purpose of contacting patients
- Approved Data User responsibilities

SCOPE

This SOP covers all of the projects and tasks which HIC undertake. It is applicable to all HIC staff. This SOP will be made available to all users and potential users of the HIC Service and will be externally visible on the public HIC website.
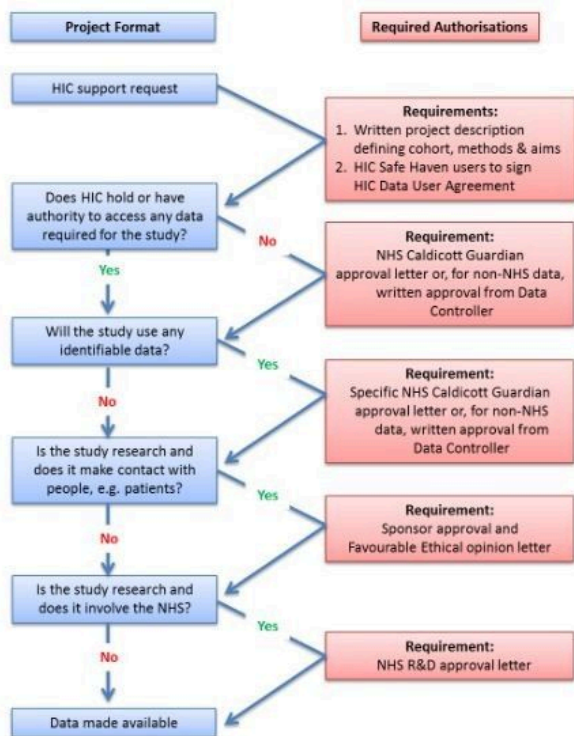
PROCEDURE

Policy

For overall Policy see Legal and Governance Policy.

HIC Services Data Access Approval Process

This flowchart illustrates the approvals required by HIC Services for different types of research, audit or service evaluation projects requiring data, following a proportional risk-based approach, i.e. lower risk data use requires less approval scrutiny:

Project Format

Required Authorisations

HIC support request

Requirements:
1. Written project description defining cohort, methods & aims
2. HIC Safe Haven users to sign HIC Data User Agreement

Does HIC hold or have authority to access any data required for the study?

No

Requirement:
NHS Caldicott Guardian approval letter or, for non-NHS data, written approval from Data Controller

Yes

Will the study use any identifiable data?

Yes

Requirement:
Specific NHS Caldicott Guardian approval letter or, for non-NHS data, written approval from Data Controller

No

Is the study research and does it make contact with people, e.g. patients?

Yes

Requirement:
Sponsor approval and Favourable Ethical opinion letter

No

Is the study research and does it involve the NHS?

Yes

Requirement:
NHS R&D approval letter

No

Data made available

---

1. Approved Data Users will provide a Project Description document, which clearly specifies the study cohort, aims and methods. It should also carry a document date and version.
2. A planned study end date will be agreed between the Approved Data Users and HIC Data Analysts for when the Project Dataset will be archived, with details added to the PM System.
3. The specific data that HIC Services will provide to best fulfil the objectives of the project will be agreed with HIC Services and recorded on a project-specific Requirement Specification by the HIC Data Analyst or Senior Developer for a development project. This will be stored on the PM System by the HIC Data Analyst or Senior Developer, along with any subsequently amended versions. The document will need to be approved by the Principal Investigator before work will start on the project.
4. HIC will discuss with the project Principal Investigator, if necessary, to advise if project Sponsorship and formal Ethics Committee review are required. The study will require both Sponsorship and Ethical review if there is any contact with patients or volunteers and/or use of consented data. Advice can also be obtained directly from the TASC Research Governance Office or the East of Scotland Research Ethics Service (EoSRES) Office. Many HIC Services Data Studies will not need Sponsorship or Ethics Committee review (refer to flowchart above).
5. If the study does require Sponsorship, a project protocol must be submitted to the TASC Research Governance Office for review. When Sponsorship is in place, an IRAS Research Ethics Committee (REC) form must be completed by the researcher, which describes HIC Services' involvement, and submitted with the necessary study documents, to REC for review. A copy of the REC favourable opinion letter must be forwarded to HIC Services for storing on the PM System.
6. An NHS R&D Form must also be submitted, with the necessary study documents, to the appropriate NHS R&D Office(s) for approval. Permission will be required from the NHS Board(s)/Trust(s) of residence of the patients. Approval letter(s) must be forwarded to HIC Services for storing on the PM System. NHS R&D permission is not required if the study does not involve NHS data or patients. Audit and Service Evaluation (non-research) projects also do not require Sponsorship, REC review or NHS R&D approval(s).
7. If the study is limited to either:
   a. using non-consented data already held within, or accessed via HIC Services and will be undertaken using anonymised data
      or
   b. also includes patient data where the patient has explicitly consented previously to its use for the study and it is anonymously linked to other data held within, or accessed via, HIC Services, the study will not require explicit Caldicott Guardian approval. The Approved Data User will have no access to any identifiable data (even the consented data).
8. Any request for identifiable data will require specific Caldicott approval, and the approval letter will be stored on the PM System.
9. No approval is required when requesting aggregate data for developing a Project Plan.

10. Specific approval will need to be obtained for particular datasets requiring sponsor approval for each use. Any component dataset within the overall Project Dataset for which the appropriate approvals are in place may be released prior to obtaining this dataset-specific approval. The unapproved data will not be supplied.
11. Where a Data Controller carries out its own project approval process, the HIC Services Data Access Approval Process will not be additionally required. The Data Controller's approval process will be described and agreed within a Data Sharing Agreement between HIC Services and the Data Controller.
12. Data may be released, to other Safe Haven environments (e.g. to the secure NHS environment at NSS Information Services Division (ISD)), where information is securely managed according to strict rules; staff are legally and contractually obliged to respect confidentiality and access to data is closely monitored and requires authorisation. The data transfer arrangements will need to be approved by the Data Controllers of the data concerned.
13. Where project-specific approval for data use is requested from Data Sponsors, HIC Services will not release data for the project until written Data Sponsor approval is obtained and stored on the PM System.

Approved Data User Responsibilities

1. Approved Data Users will read, sign and date the current HIC Services Data User Agreement (unless this is not required as agreed within a Service Level Agreement between HIC Services and the relevant External Data Controller). For a student project, this will also need to be countersigned by their supervisor and for an external collaborator the HIC Services Data User Agreement must also be signed by an authorised signatory from their organisation.
2. All Approved Data Users are required to maintain the security and confidentiality of their Project Datasets in accordance with the HIC Services Data User Agreement and the Data Protection Principles. HIC Services encourages Approved Data Users to report inadvertent events that are in breach of the terms of the HIC Services Data User Agreement to enable improvements to be made. Contact the HIC Governance Manager in the first instance to report the incident, who will initiate a Significant Event Report (see HIC Services SOP 03 Handling HIC Services Data Events).
3. Approved Data Users will not reuse the data for purposes outside the scope of each project; share it with colleagues who are not named project Approved Data Users, attempt to link it to other datasets, or to de-anonymise it.
4. Approved Data Users will only remotely access their non-consented data within the centrally-managed HIC Services Safe Haven. Individual-level data is not permitted to be stored or transferred outside the Safe Haven without explicit Data Controller permission.
5. When the project is complete the data and the analysis syntax used will be securely archived by HIC Services.
6. Approved Data Users will ensure that HIC Services and the Health Board responsible for initially providing data are acknowledged as data sources in all resulting reports and publications. E.g. "We acknowledge the support of the Health Informatics Centre, University of Dundee for managing and supplying the anonymised data and NHS 'XXX' (e.g. Tayside), the original data source"

APPLICABLE REFERENCES

- HIC Services Data User Agreement
- Data Security
- Significant Events
- Archiving a Project Dataset
- Legal and Governance Policy
- For Definitions see ISMS Glossary
- Appendix C – Roles and Contact Details

DOCUMENT CONTROLS

Process Manager	Point of Contact		
Chris Hall	hicbusiness-support@dundee.ac.uk		
Version Number Major is defined by if it is a revision of	**Effective Date**	**Edited By**	**Edition Details**

content/procedure and approval is required. It's represented as: **3**.0, **4**.0, **5**.0. Minor is defined as not requiring approval and includes small changes to spelling, grammar, and formatting. It's represented by 3.**1**,3.**2**, 3.**3**.			
1.0	01/09/2013	Duncan Heather (HIC Governance Manager)	This is a new SOP which expands on a subset of policies and supersedes Version 6 of the HIC Standard Operating Procedure, Management of HIC Datasets. Effective from 1st August 2011
2.0	01/01/2015	Duncan Heather (HIC Governance Manager)	General revision and update
2.0	24/02/2020	Tracey Stewart (Data Entry Team Leader)	Updated cover sheet with new approved process information
2.0	14/05/2020	Rachael Torano (Business Support)	Updated with new and approved Header Date approved by the Information Governance Committee updated Changes made to cover page to include Op's review date as agreed at the HIC Information Governance Meeting Document Review and Revision History added
2.0	29/06/2020	Duncan Heather (HIC Governance Manager)	Reviewed, no changes made
	17/01/2022	Duncan Heather	Reviewed, no changes made
2.1	19/02/24	Symone Sheane and	Updated into new template and moved to Confluence from

		Bruce Miller	SharePoint
Last Review Date	**Triggers** - Annual Review - Internal Audit (conducted by TASC annually) has identified opportunities for improvement (OFI) or nonconformities (NC) - External Audit has identified OFI or NC - Significant Event has highlighted OFI - Client Complaint has highlighted OFI - HIC All Staff (individuals of) have identified OFI		
17/01/22	Annual Review		

Approved by the HIC Ops Group Date	Approved by the HIC Exec Date
n/a	n/a