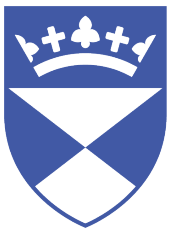


HIC Services SOP Appendix B/4.0
Effective Date: 01/07/20

HIC SERVICES STANDARD OPERATING PROCEDURE

Definitions

SOP NUMBER:	HIC Services SOP Appendix B
VERSION NUMBER:	4.0
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AUTHOR:	Duncan Heather
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CONTACT PERSON FOR THIS SOP:	HIC Governance Manager

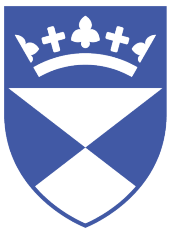


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DOCUMENT REVIEW AND REVISION HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of editions made:
1.0	Duncan Heather (HIC Operations Manager)	01/09/13	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	Duncan Heather (HIC Operations Manager)	01/01/15	General review and update
3.0	Duncan Heather (HIC Governance Manager)	01/10/16	Separate out ADP definitions. Redefine "Approved Data User"
4.0	Duncan Heather (HIC Governance Manager)	01/07/20	Updated 32. Governance Documentation to ISMS Documentation

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



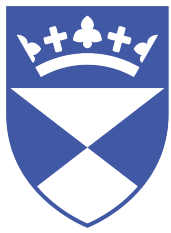
1. PURPOSE

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.

To provide a central list of definitions relating to terms used in HIC SOPs.

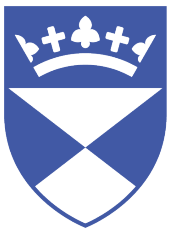
2. TERMS – GENERAL HIC

1. **ADP** – Application Development Projects. This is the HIC team that carries out software development to facilitate secure data collection, consisting entirely of HIC Developers and working mainly with consented data.
2. **Anonymised Data** – has had all data removed that could allow individuals to be identified. These include CHI, name, date of birth, address, full postcode, GP code, General Medical Council registration number, GP Practice code. Any request for data containing any of this information will be treated as a request for identifiable data, which will require explicit Caldicott approval from the NHS Board(s) of residence of the patient(s). HIC Services recognises that while the data is anonymised it is potentially disclosive, so is treated by HIC Services as potentially personal data
3. **Approved Data User** – is the Approved DLS Project Principal Investigator (PI) as named on the PM System, or a person who is authorised by the PI to also have access to the DLS Project Dataset. The Approved Data User, to whom data has been made available, will be recorded on the PM system.
 - a. The Approved Data User must complete approved Information Governance training and provide the certificate to HIC.
 - b. Employees of NHS Tayside, NHS Fife, the University of Dundee or the University of St Andrews need to read, sign and follow the terms of the HIC Data User Agreement.
 - c. Where an Approved Data User is not such an employee the HIC Data User Agreement must also be signed by a senior representative of the external Approved Data User's organisation.
4. **Approved Project** - is a project that is logged into the Project Management System and has Ethics, Caldicott and NHS R&D governance approval, as required.
5. **CIB** – Clinical Information Bureau (CIB) is a separate Data Entry Unit of HIC Services located within a secure office at Ninewells Hospital. CIB's primary function is to receive and add missing data to

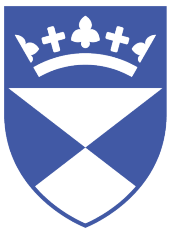


incoming NHS data relating to the community-dispensed prescription dataset. The Unit also provides general clerical support to individual research projects, including project-specific data entry for the Tayside Clinical Trials Unit (TCTU) and handling the receipt and dispatch of paper data and mail.

6. **Caldicott Guardian** - is a senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing.
 - a. Each NHS organisations is required to have a Caldicott Guardian; this was mandated for the NHS by Health Service Circular: HSC 1999/012. The mandate covers all organisations that have access to patient records, so it includes acute trusts, ambulance trusts, mental health trusts, primary care trusts, strategic health authorities, and special health authorities such as NHS Direct.
 - b. Caldicott Guardians were subsequently introduced into social care in 2002, mandated by Local Authority Circular: LAC 2002/2.
 - c. The Guardian plays a key role in ensuring that NHS, Councils with Social Services Responsibilities and partner organisations satisfy the highest practical standards for handling patient identifiable information.
 - d. Acting as the 'conscience' of an organisations, the Guardian actively supports work to enable information sharing where it is appropriate to share, and advises on options for lawful and ethical processing of information.
7. **CHI** – Community Health Index number. Unique 10-digit NHS (Scotland) patient identifier consisting of patient's date of birth (as DDMMYY), followed by four digits: two digits randomly generated, the third digit identifying gender at birth (odd for men, even for women) and a check digit. HIC uses CHI to link cohort records across datasets when creating Project datasets.
8. **Cohort Manager** – DLS software used to manage versions and Pro-CHI allocation of Approved Project cohorts.
9. **Consented Data** – The individuals to whom the data relates (data subjects) have given explicit approval for its processing for the purposes being undertaken.
10. **Data Controller** – a group or individual responsible for determining the purposes for which and the manner in which any personal data are, or are to be, processed. For example, NHS Tayside and Fife are Data Controllers for regional NHS data processed on their behalf by HIC Services.
11. **Data Processor** – an individual outside the Data Controller's organisation processing data on behalf of the Data Controller.
12. **DLS** – Data Linkage Service. This is the HIC team of mainly Data Analysts that carries out data receiving, managing, linkage, anonymisation and release, mainly with unconsented NHS data.



13. **HIC** – Health Informatics Centre (HIC) Services.
14. **HIC Data Analyst** – is an employee of the University of Dundee authorised by the HIC Executive Committee to process data on behalf of HIC Services. HIC Data Analysts will be located within the HIC Services secure office and will work on NHS networks.
15. **HIC Developer** – is an employee of the University of Dundee authorised by the HIC Executive Committee to develop software and process data on behalf of HIC Services. HIC Developers will be located within the HIC Services secure office and will potentially work on either University or NHS networks. A HIC Developer is not permitted to receive or release data, which must be handled by a HIC Data Analyst within DLS.
16. **HIC Executive Committee** – the HIC Executive Committee (HIC Exec) is the management committee with overall decision-making responsibility for HIC operational activity. HIC Exec meets monthly and has the responsibility to ensure compliance with HIC Services SOPs on behalf of the HIC Governance Committee.
17. **ISMS** – Information Security Management System, covering the full range of HIC ISO 27001 documentation covering HIC's governance and data security processes.
18. **Non-Consented Project Dataset** – a Project Dataset that uses routinely-collected administrative data without direct consent from individuals described within the data.
19. **Personal Data** – any information relating to an identified or identifiable living person. The 8 Data Protection Principles in relation to protecting personal data are listed in the HIC Services SOP Appendix A - Policy Document.
20. **Pro-CHI** – a project-specific identifier used by HIC to uniquely anonymise a typical NHS dataset CHI number across all datasets within the overall Project Dataset.
21. **Project Dataset** - is a dataset that has been anonymised uniquely and specifically for use within an Approved Project. The dataset must relate to the cohort and purpose defined in the Project Description.
22. **Project Description** – when required, as described in point 4, will specify the study cohort, aims and methods. It will also carry a date and version number. This document is used to help decide what data is required to fulfil the study objectives.
23. **Project Management (PM) System** – database and software system used by HIC Services to store project details and documents relating to, in particular, approvals and data releases.
24. **System Administrator** – is an employee of the University of Dundee authorised by the HIC Executive Committee to provide and support the technical infrastructure, including maintaining secure IT environments, backup and off-site mirroring of data.
25. **TASC** – Tayside medical Science Centre, Ninewells Hospital.



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26. **TCTU** – Tayside Clinical Trials Unit

3. TERMS – ADP

27. **Application** – The implementation of a service (web application, console application, etc.)
28. **Automated Build Environment** – software system used by HIC Services to manage consistent, tested and automated building and release of applications
29. **Change Category** – Defines a common scale against which to judge the magnitude of the change in terms of effort and risks.
30. **Client** – The requestor of a software project. Can be internal.
31. **Development Team** – comprised of the Developer Manager, Senior Developers and Junior Developers.
32. **ISMS Documentation** – Standard Operating Procedures (SOPs) and other documentation relating to HIC's ISO27001 Information Security Management System
33. **Maintenance window** – an agreed period in time where changes to an application can be made and where users are aware of potential unavailability.
34. **Production database** – database with live data
35. **Project** – One or more services that cover a customer's needs
36. **Staging database** – database with the identical structure as the production database but containing only test data
37. **Service** – Combination of people, processes and technology to support customer's business
38. **Service Catalogue** – The Service Catalogue is a dashboard which contains up-to-date project information for example: project status, lifecycle stage, error reporting, docs etc.
39. **Team Manager** – The Senior member of staff conducting the Audit Procedure
40. **Testing database** – database used during development containing only test data
41. **User** – The individual using the software system once completed. Can be internal and can also support testing of the software before completion.
42. **Version Control System (VCS)** – software system used by HIC Services to store, manage versions and track changes to applications and documentation