

HIC SERVICES STANDARD OPERATING PROCEDURE

Record of Custody

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DOCUMENT HISTORY:

| Version Number: | Edited by (job title): | Effective Date: | Details of editions made: |
|-----------------|--|-----------------|---|
| 1.0 | Duncan Heather (HIC Governance 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 Governance Manager) | 01/01/15 | General review and update |
| 2.1 | Keith Milburn (ADP Manager) | 01/04/18 | Removal of specific reference to TCTU |
| 3.0 | Duncan Heather (HIC Governance Manager) | 08/11/18 | Update to reflect new Staff Confidentiality Agreement |
| | Rachael Torano (Business Support) | 15/05/2020 | Updated with new and approved Header Changes made to cover page to include Op's review date as agreed at the HIC Information Governance Meeting Document Review and Revision History Table Header Updated As agreed by the HIC Governance Committee signatures have been removed from cover page and Document Review and Revision History table has been updated to include review dates and notes |
| 4.0 | Adrian Clatworthy (HIC Business Support Co-Ordinator) | 15/01/2021 | Updated to reflect new Business Support Team structure |

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

1. PURPOSE

The HIC Business Support team carries out data entry within a secure office at Ninewells Hospital. In addition to wider HIC administrative support activities, it receives and processes incoming NHS data relating to the community-dispensed prescription dataset. The team 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.

To define the procedures involved with the transfer of paper data to and from HIC for data entry purposes. The SOP covers:

- Record of custody – containing details of all paper data transfers in and out of HIC
- Checking and Logging data – detailed procedures for ensuring paper data is handled securely and recorded accurately.

2. SCOPE

This SOP covers projects and tasks which HIC undertake which involve the transfer of paper data records in and out of HIC. It is applicable to all HIC staff. This SOP is made available to all users and potential users of the HIC Service and will be externally visible on the public HIC website.

3. DEFINITIONS

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

4. RESPONSIBILITIES

- HIC Director – Responsible for overall HIC security policy and implementation
- Process Manager – Ensuring SOPs are followed by team
- Governance Manager – Monitoring compliance, handling significant events, keeping SOP up to date
- All HIC Staff – Responsible for adherence to the SOP as specified

5. POLICY

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

5.1 Record of custody

- 5.1.1.1 All new starts involved with data entry will be trained in the Record of Custody system before they are able to receive or dispatch paper-based data on behalf of HIC.
- 5.1.1.2 A record of custody is kept of all paper-based data. The purpose of this record is to be able to quickly ascertain what data is currently held within HIC, and what data was received, removed and when.
- 5.1.1.3 Project data printed within the HIC data entry office will also be recorded.
- 5.1.1.4 The Record of Custody consists of a folder, containing HIC Transfer of Document sheets, which is kept within the data entry office and is available for any trained member of staff to use.

5.2 Checking and Logging Data

- 5.2.1.1 Any paper based data entering or leaving HIC must be checked and recorded in the record of custody.
- 5.2.1.2 HIC Transfer of Document sheets relating to received data will be stored in the “Current” transfer of custody folder and when the data is leaving, or being shredded, it will be transferred to the “Archive” transfer of custody folder.
- 5.2.1.3 Any data being received into HIC will be assigned a batch number which will be attached to the batch, along with the study name and date of arrival.
- 5.2.1.4 The secure storage location will be recorded if the data contains person-identifiable information or relates to a Clinical Trial.
- 5.2.1.5 The data will either be accompanied by a coversheet, providing details about the delivery, or one will be prepared by the HIC Business Support Team. The coversheet information, which will be stored in the record of custody folder, will include:
 - Delivery date
 - Name of project
 - Contact details of the data sender
 - Description of the data
 - Count of individual items contained within the batch

- 5.2.1.6 On arrival the HIC Business Support staff member concerned will physically check description accuracy and item count and record:
- Date of receipt
 - Their name & signature
 - Storage location (if identifiable data)
 - Assigned batch number
 - If a batch checklist is provided, listing individual batch items, each item will be checked off as present and the sheet initialed by the receiving HIC Business Support staff member.
 - If the count does not match, the sender of the data must be contacted to ensure that no data has been lost and the count reconciled before data entry commences.
- 5.2.1.7 The data batch will be kept together when stored, with the following information attached:
- Batch ID number
 - Delivery date
 - Storage location, if the data contains person-identifiable information
 - Item count within batch.
- 5.2.1.8 For data leaving/being shredded a HIC Business Support staff member responsible will record:
- The name & signature of the person receiving/shredding the data.
 - Date of transfer
 - Destination of data

6. APPLICABLE REFERENCES

- HIC Services Transfer of Document sheet
- HIC Staff Confidentiality Agreement
- HIC Services SOP 06 Data Entry Training
- HIC Services SOP 08 Document Scanning & Shredding
- HIC Services SOP 09 Data Entry Quality Control
- HIC Services SOP Appendix A – Policy
- HIC Services SOP Appendix B – Definitions
- HIC Services SOP Appendix C – Roles and Contact Details