HIC SERVICES STANDARD OPERATING PROCEDURE

Data Entry Quality Control

SOP NUMBER: HIC Services SOP 09
VERSION NUMBER: 4.0
EFFECTIVE DATE: 15/01/2021
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 INFORMATION GOVERNANCE COMMITTEE: 15/01/2021
DATE APPROVED BY THE HIC EXECUTIVE COMMITTEE: 10/11/2020
DATE REVIEWED BY HIC OPERATIONS GROUP: N/A
CONTACT PERSON FOR THIS SOP: Duncan Heather, HIC Governance Manager, d.heather@dundee.ac.uk
# DOCUMENT REVIEW AND REVISION HISTORY:

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Edited by (job title):</th>
<th>Effective Date:</th>
<th>Details of editions made:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Duncan Heather (HIC Governance Manager)</td>
<td>01/09/13</td>
<td>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.</td>
</tr>
<tr>
<td>2.0</td>
<td>Duncan Heather (HIC Governance Manager)</td>
<td>01/01/15</td>
<td>General review and update</td>
</tr>
<tr>
<td>3.0</td>
<td>Keith Milburn (ADP Manager)</td>
<td>08/11/18</td>
<td>Updated to reflect new Staff Confidentiality Agreement and refocused to data entry quality control, with section covering training moved to SOP06 and transfer of custody removed as already covered in SOP05</td>
</tr>
<tr>
<td></td>
<td>Tracey Stewart (Data Entry Team Leader)</td>
<td>24/02/20</td>
<td>Updated cover sheet with new approval process information</td>
</tr>
<tr>
<td></td>
<td>Rachael Torano (Business Support)</td>
<td>15/05/2020</td>
<td>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</td>
</tr>
<tr>
<td>4.0</td>
<td>Adrian Clatworthy (HIC Business Support Co-Ordinator)</td>
<td>15/01/2021</td>
<td>Updated to reflect new Business Support Team structure</td>
</tr>
</tbody>
</table>

*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, 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. The purpose of this document is to define the procedures surrounding Data Entry Quality Control.

2. SCOPE
This SOP covers all data entry projects and tasks which HIC undertake which involve the HIC Business Support staff. It is applicable to all the HIC Business Support staff involved with data entry and their managers. 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.

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 Business Support Team Staff involved in patient data entry** – Responsible for adherence to the SOP as specified
- **Senior Business Support Administrator - NHS CHI Quality Control**

5. POLICY
For overall Policy see HIC Services SOP Appendix A – Policy
5.1 Study-specific Data Entry QC

5.1.1.1 Unless otherwise specified the default data entry quality checking method is from King DW and Lashley R (see references), as described.

5.1.1.2 HIC Business Support Staff will enter data as provided. If it is impossible to read a data item it will be coded to reflect that it is unreadable and recorded as a discrepancy. An audit trail of who performed entry and on what date will be maintained.

5.1.1.3 The quality check is based on visual verification with correction, which requires a member of staff to compare each item in a record with the same item on the source record. Double entry may alternatively be used. The method of data entry QC to be used will be agreed with the project team prior to data entry commencing.

5.1.1.4 The person doing the quality check will not be the same person who entered the data into the database.

5.1.1.5 The procedure is, unless otherwise specified, to error-check the first 10 electronic records entered. If all items are correct then sampling starts, where every 15th electronic record is error-checked. Errors raised during data entry will be annotated appropriately. If errors are consistently made, the procedure will in the extreme case escalate to a 100% check of entered data.

5.1.1.6 Data Entry will not continue checking beyond the first 10 records entered by each HIC Business Support person until these records have been quality checked. If an error is identified this is recorded and a further 10 records are checked until a run is error-free.

5.2 Study-specific QC Reporting

5.2.1.1 A complete electronic record will be kept of each record checked or skipped over as part of the QC process, along with the name of the check person and the date, a note will be made if no errors are found. Where an error is found and corrected a note will be made describing the error for training purposes.

5.2.1.2 A summary QC report will be provided, as specified by the project team, including number of records entered, checked and errors found and corrected.

5.2.1.3 Summary reports from each study will be retained and collated to illustrate on-going data quality.

5.3 NHS CHI Quality Control (QC) / Performance

5.3.1.1 For any new staff member, QC will be performed after the first entered batch by a Senior Business Support Administrator or nominated experienced member of staff and any mistakes are discussed with the new start, answering any queries they may have. The number of scripts “skipped” without entering data is also checked as part of any quality check and, if this is too high, will also be discussed with the new start and will lead to further QC checks.

5.3.1.2 At the Senior HIC Business Support Administrator’s discretion, QC can continue beyond this point the new staff member has a high error/skip rate or requires additional guidance.
5.3.1.3 Routine QC checks will occur following completion of a batch, as part of a team-wide quality check including:
   - Review all errors individually and use to train team or individuals
   - Spot review skipped scripts and review individually to identify training issues and improve CHI entry %
   - If necessary, a Senior HIC Business Support Administrator can request further QC on a member of staff

5.3.1.4 Once a new staff member has gained speed and confidence, their daily productivity figures will be shown as part of the daily production report.

6. APPLICABLE REFERENCES

1. HIC Services SOP 05 Data Entry Office Security
2. HIC Services SOP 06 Data Entry Training
3. HIC Staff Confidentiality Agreement
4. HIC Services SOP 07 Record of Custody
5. HIC Services SOP 08 Document Scanning & Shredding
6. HIC Services SOP Appendix A – Policy
7. HIC Services SOP Appendix C – Roles and Contact Details
8. King DW and Lashley R, A quantifiable alternative to double-entry. Controlled Clinical Trials 2000; 21, 92-102