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Contents

1. Introduction

The West of Scotland Safe Haven (WoS Safe Haven) is a collaboration between NHSGGC Research and Innovation and the University of Glasgow Robertson Centre for Biostatistics (RCB). The Safe Haven offers a resource for health-related data to enable data linkage of health-related patient generated datasets, to provide answers to clinical research questions and to inform health service improvement. The Safe Haven can:

- facilitate researcher access to pseudonymised health datasets
- offer a secure ISO-accredited data analytics platform
- deliver expert support to enable data-driven discovery with de-identified NHS data

The West of Scotland Safe Haven is accredited by the Scottish Government as a Safe Haven, and is one of four regional Safe Havens across Scotland.

Safe Havens are designed to provide secure access to NHS and other health datasets derived from diverse sources across the health service.

By enabling researchers to link data from difference sources, Safe Havens encourage data-driven health research to improve health services, design better treatments, and to create innovative new health products to support better health in Scotland.

1.1. Scope of the Quality Manual

This Quality Manual applies to all staff and investigators working within the WoS Safe Haven. In addition to this Quality Manual, the main R&I Quality Manual is applicable and the contents of both are aligned to ensure compatibility. It is every individual's responsibility to work within and adhere to current national legislation/guidelines and local policies and procedures; these are referenced throughout the manual.

1.2. About the RCB

The Robertson Centre for Biostatistics at the University of Glasgow is a fully registered Clinical Trials Unit, conducting and supporting collaborative research in clinical trials.

The RCB provides an out-sourced data hosting service to the West of Scotland Safe Haven, presenting pseudonymised dataset processed by the Safe Haven to researchers in a an ISO 27001-accredited Secure Data Environment.

1.3. Applicable Regulations and Standards

A number of Regulations and International Standards are applicable to the work carried out within the Safe Haven, a non exhaustive list of such Regulations and Standards is:

- Common Law Duty of Confidentiality
- Data Protection Act 2018
- EU Directive 2001/20/EC
- EU Directive 2003/94/EC
- EU Directive 2005/28/EC
- EudraLex volume 4, Annex 1: EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use
- ICH GCP Guideline (CPMP/ICH/135/95)
- MHRA guidelines: 'Guidance on the maintenance of regulatory compliance in laboratories that perform the analysis or evaluation of clinical trial samples'
- NHS Greater Glasgow & Clyde clinical and research governance provisions
- The Human Tissue Act 2004
- The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- The Research Governance Framework for Health and Social Care, 2nd Edition

1.4. Definitions

Abbreviation	Definition
CAPA	Corrective Action Preventative Action
CSV	Computer Software Validation
CTA	Clinical Trial Agreement
CTA	Clinical Trials Authorisation
GCRF	Glasgow Clinical Research Facility
GCTU	Glasgow Clinical Trials Unit
GCP	Good Clinical Practice
IMP/NIMP	Investigational Medicinal Product/non-IMP
MHRA	Medicines and Healthcare Products Regulatory Agency
QP	Qualified Person
R&I	Research and Innovation
RCB	Robertson Centre for Biostatistics
SOP	Standard Operating Procedure
WI	Work Instructions
WoS	West of Scotland
GUI	Guidelines
QMS	Quality Management System

2. Management Responsibility

The Research & Innovation Director and/or Senior Research and Innovation Manager and/or Safe Haven Manager is on the following committees:

- Glasgow Health Science Partnership Regulatory Affairs Group (GHSP RAG)
- Glasgow Health Science Partnership Delivery Group (GHSP DG)
- Glasgow Clinical Trials Unit Management Committee
- R&I Senior Management Committee

The Safe Haven's main committee at which quality issues are discussed and reviewed is the Safe Haven Governance and Activity Group.

2.1. Safe Haven Management Committees

Committee	Members
West of Scotland (WoS) Safe Haven Governance and Activity Group	• Senior R&I Manager, NHS GG&C • Senior Innovation Manager, NHS GG&C • Head of Information Governance, NHS GG&C • Head of Information Management, NHS GG&C • eHealth Innovation Programme Director, NHS GG&C • Director RCB, UoG • Data Manager, Safe Haven • Senior Application Programmer, RCB and/or deputies from the RCB team • Biorepository Technical Specialist • Chair of Local Privacy and Advisory Committee
Local Privacy and Advisory Committee (LPAC)	See current LPAC Membership list.

2.2. Safe Haven Quality Aims and objectives.

The Safe Haven operates in accordance with the Scottish Government's Charter for Safe Havens in Scotland.

Safe Havens in Scotland operate to use routine data from electronic National Health Service (NHS) patient records, and process and link these records with other data for analysis to support research when it is not practicable to obtain individual patient consent while protecting patient identity and privacy.

2.3. Management Review

Safe Haven Management Committees take responsibility for the Safe Haven elements of the R&I quality management system (QMS) by regularly including feedback opportunities through meeting agendas or by commissioning regular reports in various areas, some of these are:

- Follow-up actions from Previous Management Reviews
- Results of Internal Audits
- Results of External Audits/Monitoring
- Customer Feedback and Complaints
- Status of Deviation Reports and CAPA projects
- Recommendations for Improvement

All Safe Haven staff have responsibility to report any areas of concern they have relating to the quality system to their line manager.

2.4. Resources

The Safe Haven Management Committees are committed to resource the elements of and compliance to, the quality management system to meet regulatory requirements and to maintain and improve the effectiveness of the quality management system and its processes.

2.4.1. Premises

The Safe Haven provides and maintains adequate infrastructure needed to provide service to our users and conform to required regulations including:

- Buildings, workspace and associated utilities
- Process equipment (both hardware and software)
- Support Services (i.e. communication etc.)

2.4.2. Staff

- The Safe Haven employs a team of core staff who have been selected to ensure that they have the right qualifications, skills and competencies to carry out their roles. All staff have defined job descriptions.
- Staff are actively encouraged to undertake professional development courses and attend conferences and seminars to ensure that their skills are continuously developed and updated.

2.4.3. Work environment

The Safe Haven shall determine and manage the work environment ensuring that the workspace is suitable for all Safe Haven staff.

2.4.4. Organisational Chart

An organisational chart, as shown in Figure 1, demonstrates reporting lines in the Safe Haven. The organisational chart is maintained by the Safe Haven Manager. The chart is updated when required. See also the Research and Innovation Quality Manual.

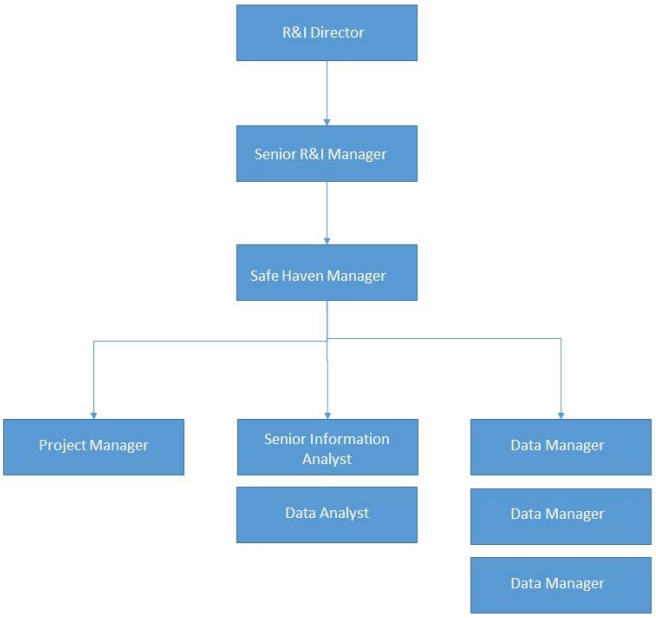

Figure 1 – Safe Haven Organisational Chart

3. Document Control

The QMS has documented procedures to control and manage processes associated with the operational and administrative procedures within the Safe Haven.

3.1. Documents

The QMS includes the following documents:

- Documented Safe Haven Quality Aims and objectives.
- Documented standard operating procedures (SOP) to ensure the effective planning, operation and control of Safe Haven processes.
- Documented Forms (Form) to provide a repeatable and structured format for capturing information through compliance to the QMS.
- Documented Guidance Documents (GUI) to detail how specified work should be carried out to ensure a systematic approach.
- Documented Work Instructions (WI) can be put in place to act as an instruction set for staff in the event a standardised and repeatable task is to be carried out.

The Safe Haven has an approved index of all SOPs and guidance documents governing its processes. All SOPs and guidance documents are stored on the R&I Q-Pulse database and made available on the GCTU website, which both can be accessed by Safe Haven staff. The master list of category headings and SOP numbers will be contained in an inventory on Q-Pulse, maintained by the Quality Manager within R&I. The Safe Haven takes ownership of preparing, amending and maintaining SOPs following SOP 50.023.

3.1.1. Safe Haven Chapter

The Safe Haven has their own subsection within the main R&I QMS, this has been given the identification of Chapter 59. This means that all document types will be numbered following their document type prefix with the number 59, followed by an incremental 3 digit number to identify each document. For Forms, Guidelines and Work instructions, they will be associated to the relevant SOP and share the main numerical number to identify the association and then have a further identifier of a letter which will ascend in alphabetical order.

For example: (Numbers are intended for demonstrative purposes and may not refer to actual documents in use)

- SOP 59.001, SOP 59.002, etc
- Form 59.001A, Form 59.001B, Form 59.002A, etc
- GUI 59.001A, etc
- WI 59.001A, etc

3.2. Change Control

The Q-Pulse system is in place to ensure that the latest copies of all documents are available readily to ensure effective functioning of the Safe Haven QMS. There is also a documented process used to ensure that changes to the system are introduced in a controlled and coordinated manner and to ensure that changes are appropriately controlled, documented and approved by designated functions, refer to SOP 50.023.

3.3. Retention of Records

Records are maintained in order to provide evidence of conformity to the requirements of the QMS and demonstrate its operation. All QMS documents are retained indefinitely, as detailed within SOP 50.023. The output of the QMS and evidence of trial related activity will be retained within the Trial Master File (TMF) as per SOP 51.016 and then retained as per the relevant archiving SOP (SOP 51.024 & SOP 51.025).

3.4. Deviation Reporting and CAPA

The Safe Haven takes action to investigate the cause of non-conformities and deviations in order to correct and prevent recurrence. Line Managers are responsible for the quality of work carried out within their team and for escalating any quality issues to the Senior R&I Manager and R&I Governance team. This is controlled as per SOP 51.008.

4. Risk Management

4.1. Risk Assessment Procedure

All trials conducted by NHSGGC Research and Innovation, both Sponsored and Hosted will undergo a Risk Assessment as per SOP 51.004. If the use of Safe Haven is involved in the trial, an appropriate representative from Safe Haven will be involved in this Risk Assessment. Further to this, Safe Haven staff assess the level of risk for each Project, and follow internal Standard Operating Procedures for data extraction and project management to mitigate major data breach risks.

5. Training

All Safe Haven staff will be fully trained to deliver their roles in accordance with their Job Descriptions, and training will be consistent with the Research and Innovation Quality Manual. All staff will maintain evidence of their training in accordance to SOP 50.013.

6. Audit

All Audit activity carried out within R&I will be conducted in compliance to SOP 53.005.

6.1. Internal Audits

i. The Safe Haven will be included in the R&I Governance Internal audits schedule to verify that the quality system is in compliance with the established information governance and regulatory requirements and to verify the effectiveness of each system.
ii. The Safe Haven Manager will develop and administer an agreed annual internal audit schedule for process quality checks. This will include implementing, scheduling, communicating, maintaining and monitoring the schedule.

6.2. Internal Audit Report

i. An internal audit report will be created to summarise audit findings.
ii. The audit report will document the observations and findings of the components audited, with a comment and recommendations where appropriate. This report will then be issued to the personnel responsible for the area audited for review and action and for escalation to senior management as required.
iii. Findings and actions identified by audit will be documented and addressed in a timely manner with implementation of corrective and preventative actions verified and documented.
iv. It is important that continual review of audit findings and the management of associated corrective and preventative actions are performed to ensure continuous quality improvement.

6.3. Third Party Audit/Monitoring Findings

i. The Safe Haven will support external audit/inspection and subsequent corrective and preventative actions.

7. Quality Assurance

7.1. Confidentiality

Handling of confidential information will be as per RCB SOP 04.004 – Confidentiality Statement

7.2. Security

Securing of systems hosting Safe Haven dataset will be as per RCB SOP 07.008 - Data Management: Transfer of Electronic Data and RCB SOP 02.021 - Network Security

7.3. Systems (Installation)

Systems installation within the NHS firewall will be in accordance with all NHS GG&C eHealth Information Security policies, and hardware for hosting of Safe Haven dataset will follow RCB SOP 02.001 System: Hardware and Software

7.4. Systems (Decommissioning)

Decommissioning of hardware used to host Safe Haven datasets will be as per RCB SOP 02.004 - System: Decommissioning and RCB Form 02.004A - Hardware Disposal Form

7.5. Complaints

Complaints will be handled in accordance with the Research and Innovation Quality Manual

7.6. Systems (Data Backup)

Data fidelity and robust backups are central to the WoS Safe Haven as a data service, core data backup policies are described in SOP 59.010 System and Data Backup

8. Referenced documents

- SOP 01.005 - Format of SOPs and Guidelines
- SOP 01.006 - Production and Maintenance of SOPs, Guidelines and Forms
- GUI 01.006B - GCRF process for new/modified SOPs/supporting documents
- Form 01.008B - Read and Comprehend Training Record Form
- SOP 51.008 - Handling non-compliance with Good Clinical Practice (GCP) and/or the trial protocol in clinical research sponsored, co-sponsored or hosted by NHS Greater Glasgow and Clyde
- SOP 51.031 - Corrective and Preventative Action Plan Management
- Research and Innovation Quality Manual
- RCB SOP 04.004 - Confidentiality Statement
- RCB SOP 07.008 - Data Management: Transfer of Electronic Data
- RCB SOP 02.021 - Network Security
- RCB SOP 02.004 - System: Decommissioning
- RCB Form 02.004A - Hardware Disposal Form
- NHS GG&C eHealth Information Security Policies, https://scottish.sharepoint.com/sites/GGC-eHealth/SitePages/Information-Security-Policies.aspx
- SOP 59.010 - System and Data Backup
- Scottish Governments Charter for Safe Havens - https://www.gov.scot/publications/charter-safe-havens-scotland-handling-unconsented-data-national-health-service-patient-records-support-research-statistics/pages/1/

9. Related documents

- NHS GG&C Policies – www.nhsggc.org.uk