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Contents

1. Introduction

The West of Scotland Safe Haven (WoS-SH) is a collaboration between NHSGGC Research and Innovation and the University of Glasgow. The WoS-SH offers a resource for electronic health record (EHR) and-related data to support data driven clinical research and innovation, support clinical trials and to inform health service improvement.

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

Safe Havens were introduced in Scotland to address the need to facilitate expedited and secure access to Scottish EHR data, within Scotland there is 1 national Safe Haven and 4 regional Safe Havens which form the Scottish Safe Haven Network (SSHN). The Safe Havens are bound by the Safe Haven Charter and are reportable to the Chief Scientists Office (CSO). Each Safe Haven carries its own Research Ethics Committee (REC) favourable opinion (FO) to function as a research database.

The primary function of the WoS-SH is to provide pseudonymised EHR data to answer clinical research questions. To support this research the WoS-SH can:

- facilitate researcher access to pseudonymised health datasets
- offer a secure ISO-accredited Trusted Research Environment (TRE)
- deliver expert support to enable data-driven discovery with de-identified NHS data

In addition to pseudonymised EHR data the WoS-SH can provide support for clinical trials in the form of:

- feasibility as part of the site selection or grant application process
- support for participant identification/screening
- participant follow up

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-SH. 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 University of Glasgow Trusted Research Environments (TRE)

The University of Glasgow College of Medical, Veterinary and Life Sciences (MVLS) is a close collaborator with NHSGGC R&I department. Within the University of Glasgow is the Robertson Centre for Biostatistics (RCB) at the University of Glasgow is a fully registered Clinical Trials Unit, conducting and supporting collaborative research in clinical trials.

The RCB provides a data hosting service to the WoS-SH, enabling the provision of pseudonymised datasets supplied by the WoS-SH, within a secure computing environment in the form of an ISO 27001-accredited TRE.

In addition to the RCB TRE the University of Glasgow also holds the Glasgow TRE which has capacity to support imaging studies, provide computing power for large scale machine learning and artificial intelligence based projects. The Glasgow TRE holds Cybersecurity Essentials and Data Security Protection toolkit credentials. This TRE is housed within and ISO27001-accredited Facility ran by Data Vita.

1.3. About the Scottish Safe Haven Network

As the Scottish Government recognises a growing demand for EHR data to power clinical research the SSHN in collaboration with Research Data Scotland (RDS) began developing the process for facilitating projects seeking to utilise data held by one or more of the SSHN member Safe Havens. Under the federated governance model, a researcher can go to any of the Regional Safe Havens for access to data from multiple health boards, with pseudonymised data extracts transferred to a single Trusted Research Environment (TRE) for analysis. The scope, purpose and manner of the federated governance model will be monitored and reviewed quarterly by an Oversight Group of associated Caldicott Guardians. All SSHN TREs eligible to participate in a federated project old ISO 27001 accreditation, alternate TREs can be utilised but additional agreements and security checks may be required.

1.4. 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

1.5. Definitions

Abbreviation	Definition
CAPA	Corrective Action Preventative Action
CSV	Computer Software Validation
CTA	Clinical Trial Agreement
CTA	Clinical Trials Authorisation
FO	Favourable Opinion
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
TRE	Trusted Research Environment
WI	Work Instructions
WoS-SH	West of Scotland Safe Haven
GUI	Guidelines
QMS	Quality Management System
RDS	Research Data Scotland
REC	Research Ethics Committee
SSHN	Scottish Safe Haven Network

2. Management Responsibility

The Research & Innovation Director and/or Senior Research and Innovation Manager and/or Innovation Lead 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)
- R&I Senior Management Committee
- Innovation Governance Group
- The Digital Strategy Group

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, NHSGGC • Senior Innovation Manager, NHSGGC • West of Scotland Safe Haven Manager, NHSGGC • Head of Information Governance, NHSGGC • Head of Information Management, NHSGGC • eHealth Innovation Programme Director, NHSGGC • Data Manager, Safe Haven • Biorepository Technical Specialist • Chair of Local Privacy and Advisory Committee • UoG representatives by invitation as appropriate
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 EHR data from electronic National Health Service (NHS) Scotland patient records. This EHR data can then be linked with other data for analysis to support research when it is deemed to be within the public interest. Safe Havens do not rely on patient consent to support this research. At present there is no national, easily accessible opt out and NHSGGC includes use of patient data for research purposes within its privacy notice.

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.

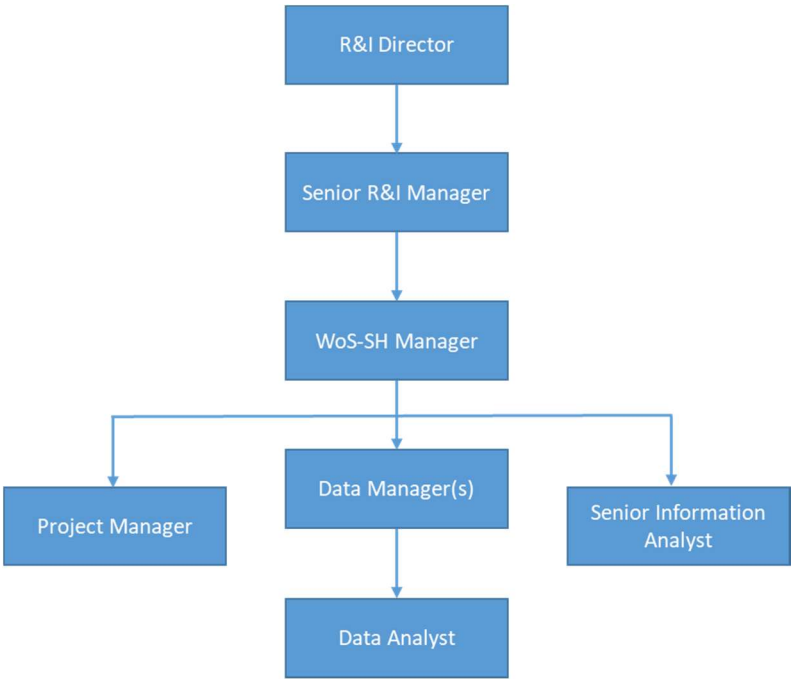

Figure 1 – Safe Haven Organisational Chart

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 WoS-SH 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 WoS-SH 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 WoS-SH takes ownership of preparing, amending and maintaining SOPs following SOP 50.023.

3.1.1. Safe Haven Chapter

The WoS-SH 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. Including but not limited to CSO reporting requirements.

7. Quality Assurance

7.1. Confidentiality

Handling of confidential information will be in accordance with NHSGGC policy. When data is transferred to an appropriate location, that location must have appropriate safe guarding procedures in place. These will be captured in an NHSGGC DPIA.

7.2. Security

Securing of systems hosting Safe Haven dataset will be in line with NHSGGC eHealth information security policies. Security details will be captured in an NHSGGC SSP as needed.

7.3. Systems (Installation)

Systems installation within the NHS firewall will be in accordance with all NHSGGC eHealth Information Security policies, and hardware for hosting of Safe Haven project datasets will follow the hosting TRE SOPs

7.4. Systems (Decommissioning)

Decommissioning of hardware used to host Safe Haven project datasets will be as per the hosting TRE SOPs.

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-SH 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
- NHSGGC 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

- NHSGGC Policies – www.nhsggc.org.uk