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Author/Approval

Name	Job Title or Role	Approver/Reviewer Signature	Statement signed against	Date
Claire Taylor	Quality Team Lead	As per electronic signature.	Author	As per electronic signature.
Maggie Yates	Head of Quality	As per electronic signature.	Approver	As per electronic signature.

Revision History

Version	Revision Date	Author(s)	Summary of Changes
9.0	09/JAN/2023	Maggie Yates	Updates to organisational chart. Updated references to Northern Care Alliance.
10.0	As per electronic signature.	Claire Taylor	Section 1- removed reference to nurse and SA and left as community clinical team. Minor changes to content. Update to section 3 measures. Inclusion of reference to DSPT in Section 3b Removal of reference to SIR Board in Section 3d2 Changes in hierarchy of documents section 5. Update of NWEH org structure, section 4. Added content in section 8.

Document Context: For Validation Documents Only

Describe document context within the Validation Framework NWEH-DOC-069

Validation Framework	N/A
Validation Context	Process / Prospective / Reflective
Quality Plan	N/A

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1.   About us

NorthWest EHealth (NWEH) is limited company, born from a partnership between the University of Manchester, Northern Care Alliance, Salford Care Organisation (formerly Salford Royal Foundation Trust) and Salford Clinical Commissioning Group (formerly NHS Salford). The organisation was established in 2008 to cultivate links between academia and the NHS in the area of digital health research, and to develop new research using anonymised patient records to support improving healthcare.

NWEH offers comprehensive product and customer support services, providing bespoke designs in accordance with customer requirements, and following all appropriate regulations, procedures, and guidance. NWEH also offers clinical services and has a Community Research team experienced in recruitment and running of both pragmatic and standard Randomised Controlled Trials. NWEH provides a full-service portfolio for pragmatic research and trials, from feasibility and data analysis studies, trial design, trial set up, full technical system for pragmatic trials to study close-down and consultancy on regulatory requirements for pragmatic trials. NWEH has a proven track record, including delivery of Salford Lung Study technologies and data. NWEH utilises examples of industry best practice and standards to inform its methods of working.

NWEH operates as a Limited company. Any surplus profit generated from its activities is distributed to the Shareholders for reinvestment in research and healthcare.

NWEH are world leaders in the innovative and trustworthy use of routinely collected healthcare data for clinical trials. Our clinical trial platform enables more effective feasibility, economic modelling, recruitment, real-time safety monitoring and data analytics to support the whole clinical trial lifecycle. NWEH works with consenting patients who provide their data from primary care, secondary care, community pharmacies and other data sources to deliver dedicated electronic health record enabled randomised controlled trials, safely and securely.

2.   Scope and Boundaries

NWEH's Integrated Quality and Information Security Management System (QISMS) supports the organisation in its development of software to analyse health records and associated services in accordance with the statement of applicability. Associated services include support provided to clinical trials by clinical trial research team. This support includes safety monitoring and patient visits. The QISMS ensures that NWEH's processes and business activities are underpinned by robust policies and documentation and enables the organisation to meet customer requirements and address any non-conformances efficiently and effectively. Our management system ensures that NWEH activities are conducted responsibly, in accordance with both our ISO 9001 & ISO 27001 certification and the requirements of the highly regulated industries within which the organisation operates.

3.   Our Quality objectives

NWEH's overarching organisational objective is to improve healthcare through better use of data. We aim to develop digital solutions that enable our customers to enhance their capabilities as health care providers and researchers and to bring new medicines and health technology to patients sooner by using healthcare data to assure their safety, efficacy, and effectiveness.

We tailor our objectives to the individual requirements of our customers on a project-by-project basis; however, there are a number of key objectives which inform all NWEH activities. These are:

a) *To ensure the safety of patients, including the security and integrity of their data*

Patient safety will always be the primary quality objective of NWEH. When working on clinical trials, we define procedures and establish targets to ensure that adverse events can be reported in a timely and appropriate manner. We respect the importance of the information with which we work. Our policies and procedures are designed to ensure that this information is sensitively managed. Our objective is to continue to improve the controls that ensure the integrity and accuracy of our information, reflecting our appreciation of the impact of our outputs upon the quality of healthcare.

This objective can be measured by:

1. The timely reporting of adverse events on Case Report Forms (CRFs).
2. The number of non-conformances reported regarding participant safety, data security and data integrity of trial.
3. Timely resolution of incidents on all clinical trials worked upon by NWEH.
4. Number of Clinical Research Associate (CRA) monitoring findings during trials, and internal audit findings related to this objective.

b) *To maintain accountability*

We work proactively to continually strengthen our information security management and governance in order to ensure that the privileged client and patient information that we work with remains confidential. The completion of a confidentiality agreement is a prerequisite of employment with NWEH, and we ensure compliance with the privacy and data protection policies of our customers and partners.

This objective can be measured by:

1. NWEH'S maintenance of ISO27001 certification,
2. Current program of work to attain the NHS Digital Data Security Protection Toolkit.
3. Number of information security incidents raised and the timely resolution of these.
4. Number of overdue training events for staff on Information Governance (IG) and General Data Protection Regulation (GDPR).
5. Number of overdue Information Security (IS) document reading for staff members.
6. Number of audit findings relating to this objective.

c) *To work ethically, with sound judgement*

All our actions are focused on delivering benefits to healthcare providers, researchers, patients, and other clients. Our overarching objective is to improve healthcare and quality-of-life utilising healthcare data. At all times, during all our activities, we consider, respect, and safeguard the dignity, rights, safety, and wellbeing of our stakeholders.

This objective can be measured by:

1. NWEH's compliance with applicable regulations and best practice as cited in the Index of Relevant Policy and Interested Parties document.
2. The number of internal and external audit findings and logged non-conformances in related areas.

d) *To build strong, collaborative relationships with our partners*

Across our management team we work at both strategic and operational levels to shape mutually beneficial partnerships with healthcare providers, commissioners, and researchers. Our objective is to effectively and proactively manage relationships with partners, and to develop agreed priorities and outcomes with our partner organisations.

This objective can be measured by:

1. The continuation of NWEH's close partner relationships with Northern Care Alliance Foundation Trust, UoM and Imperial College Healthcare Partners in Northwest London (NWL).
2. The continuation of data provision from Greater Manchester, NWL and Discover Now hubs, and the continuation of data hosting agreements within the Health and Social Care Network (HSCN).
3. Number of Data service meetings and action outcome demonstrating improvement.

e) To develop software solutions which are fit for purpose

Software development is the fundamental purpose of our organisation. We deliver software that meets the requirements of our customers as efficiently as possible. We respond and react to changing customer needs in a timely manner and provide support to ensure that our products and services continue to be fit for purpose after release.

This objective can be measured by:

1. Successful outcomes for NWEH developed software in client User Acceptance Testing (UAT).
2. Achievement of successful client and regulatory agency audits.
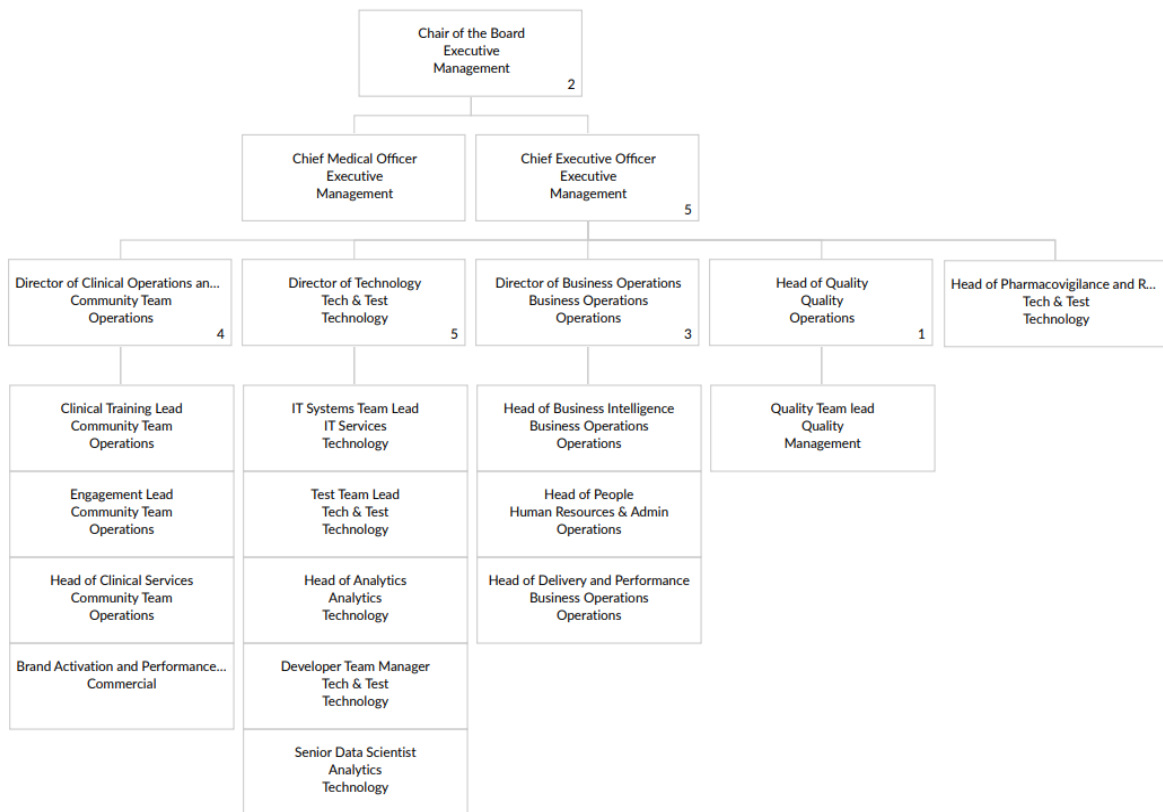3. The number of complaints received in relation to services provided.

These objectives are communicated to all staff by the circulation of this document and mandatory reading and acknowledgment of this document.

Our policy on quality and information security is documented in NWEH-POL-001.

4. High Level organogram

Below is the current high level organisation chart. This shows the departmental framework that underpins NWEH.
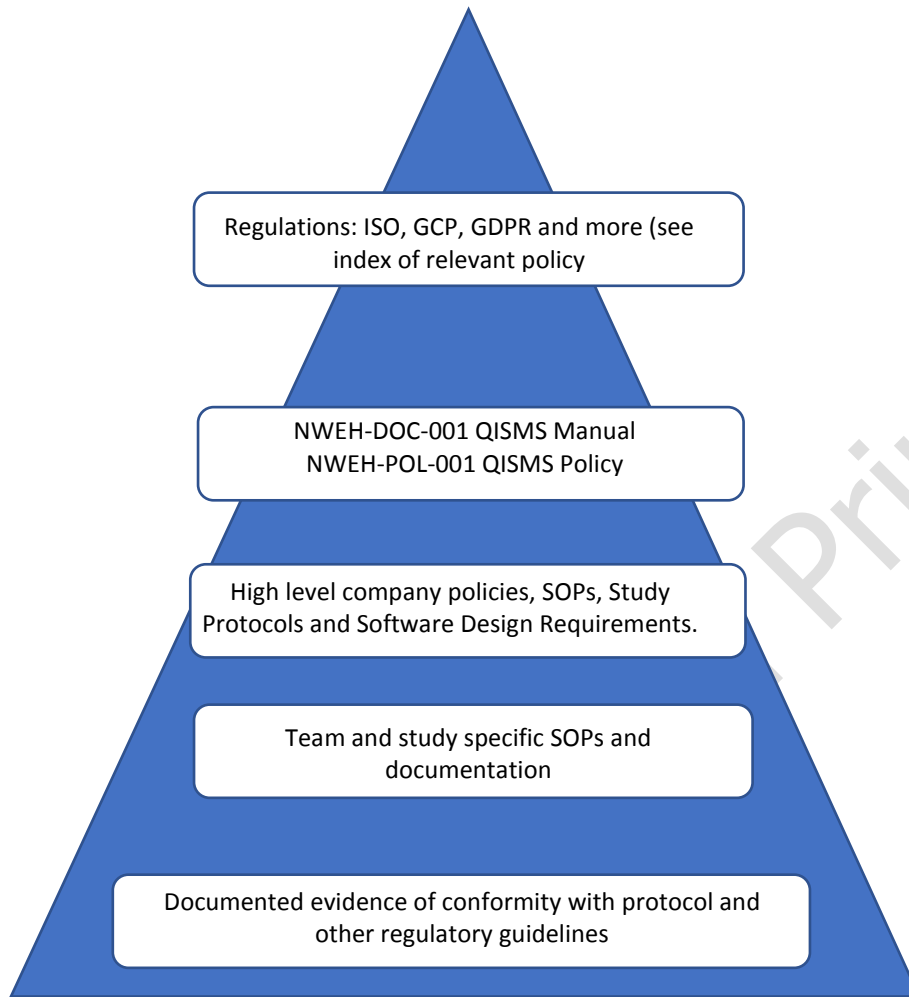
The current full organisational chart is available on request via NWEH's BambooHR software.

5. Processes

Regulations: ISO, GCP, GDPR and more (see index of relevant policy

NWEH-DOC-001 QISMS Manual
NWEH-POL-001 QISMS Policy

High level company policies, SOPs, Study Protocols and Software Design Requirements.

Team and study specific SOPs and documentation

Documented evidence of conformity with protocol and other regulatory guidelines

6. Our information security and areas of compliance

NWEH's Quality and Information Security Management System is certified against the ISO 9001 and 27001 standards. The ISO 27001 standard identifies several Information Security controls, and our "statement of applicability" explains how they have been implemented.

When we embark on a new project, we consider what new information assets the project will create and assess whether any existing information assets will change. We identify the risks to our information assets and decide how best we can treat them. Opportunities for development of NWEH services are captured by the project management team during project delivery.

NWEH Project Managers manage project risk, and the risk management procedure is documented in NWEH-SOP-068 Project Management. Higher rating project risks are highlighted to the NWEH Executive team and Board on a regular basis. Any risks to our information assets are escalated via NWEH-DOC-006 Information Security Risk Log, which is closely monitored by our Quality and IT Systems Teams.

Several Standard Operating Procedures (SOPs), policies, and work instructions, which govern NWEH's key business activities, enable us to ensure that our processes are robust, reliable, and consistent.

In order to maintain compliance with the ISO and other applicable standards, we conduct regular audits of our internal processes and services and hold (at a minimum) yearly management reviews of our quality and information security measures.

We take our responsibilities seriously and record, investigate, and remediate any information security incidents or regulatory/procedural non-conformances in a professional and timely manner.

Working in the health sector, we have extensive experience of delivering highly regulated projects. We have developed validation procedures to ensure that our services comply with GxP and FDA standards, should this be a requirement of any particular project.

In addition to this, we are compliant with the Information Governance and Information Security procedures of our partner organisations.

7. Our project approach

We utilise PRINCE2 methodology to help us to manage our projects. PRINCE2 is a widely used and recognised process approach to effective project management, and we have tailored it to fit our organisational needs. Our tailored version is described in our Standard Operating Procedure for project management.

Some of the PRINCE2 elements that we use are:

- Business cases that weigh up the advantages and disadvantages of working in particular ways on a project.
- Project initiation documents, to record the agreed ways of working, along with information about how the project will be managed and what the success criteria will be.
- Risk, issue, and decision logs, exception reports.
- Highlight reports at regular project checkpoints.
- Evaluation and lessons learned reports.
- Improvement Opportunities.

We are flexible and can adapt our approach based on the needs of our customers. For example, we can employ Agile Project Management techniques for our software development projects, or we can offer a traditional software development life cycle approach based on the ITIL phases. On regulated activities, we agree validation and quality plans with our customers which explain exactly how we will evidence that the services we provide are compliant with the relevant regulation.

These types of decisions about the way a project is to run are agreed with our customers at the outset.

8. Appendix –list of key NWEH procedures

Our key Policies and SOPS are contained within our Q Pulse Document Management system and cover the following areas:

1. HR
2. H&S
3. Finance
4. Quality and Information Security Management System, which include:
- Document Control
- Internal Auditing
- Non-Conformance management and complaint process
- Management of information security risks
- Software Development and Computer Systems Validation Processes
- Clinical Operations including trial specific documentation and processes
- Supplier Management
- QISMS risks, responsibilities, and system scope
- Project Management
- Business Development
- Asset management