NWEH
NorthWest EHealth

NWEH-DOC-001 Quality and Information Security Manual

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Document Control

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Name	Job Title or Role	Approver/Reviewer Signature	Statement signed against	Date
Joanne Macey	Quality Manager	As per electronic approval at end of Document.	Author	As per electronic approval at end of Document.
Amira Thorn	Chief Operating Officer	As per electronic approval at end of Document.	Approver	As per electronic approval at end of Document.

Revision History

Version	Revision Date	Author(s)	Summary of Changes
1.0	04/12/2014	Sarah Noone	This is the first approved issue of this document
2.0	14/12/2016	Jo Macey	Updated to reflect the status as a limited company
3.0	16/01/2017	James Baker	Updated procedures list
4.0	18/01/2017	Jo Macey	Correction to format issue, updated organogram
5.0	27/02/2017	James Baker	Update to sect 7 – Central RAID log, organogram
6.0	07 Dec 2017	Jo Macey	Updated in line with ISO9001:2015 changes
7.0	20 Nov 2018	Jo Macey	Updated to refer to the clinical side of the business

Document Contents

1) About us

NorthWest EHealth (NWEH) is limited company, born from a partnership between the University of Manchester, 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 regulation, procedures, and guidance. NWEH also offers clinical services, and has a large Community Research team made up of Research Nurses and Study Administrators experienced in recruitment and running of both pragmatic and standard Randomised Controlled Trials. NWEH provides 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 and have 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 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 enable 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 research nurses and study administrators. 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. The NorthWest EHealth Business Strategy Plan further details our organisational Key Performance Indicators and objectives.

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

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 the timely reporting of adverse events and resolution of incidents on all clinical trials that NWEH works on.

b) To maintain accountability

We work proactively to continually strengthen our information security management and governance in order to ensure that the confidential 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 the presence of a completed confidentiality agreement for all staff and contractors and no notifications made to the Information Commissioner's Office (ICO) about reportable breaches.

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 the 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 NWEH's compliance with applicable regulations and best practice as cited in the Index of Relevant Policy and Interested Parties document. This objective can also be qualified by assessing 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 the continuation of NWEH's close partner relationships with SRFT, UoM and CCG. In particular the continuation of data provision through the Salford Integrated Record (SIR) Board, and the continuation of data hosting agreements within N3.

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 successful outcomes for NWEH developed software in client User Acceptance Testing(UAT) and by NWEH successfully passing client and regulatory agency audits. For the clinical side of the organisation, this can be demonstrated by site greenlighting evidence prior to the start of a study at site. This can also be measured by the number of complaints received in relation to services provided.

These objectives are communicated to all staff in the induction policy and by the circulation of this document.

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

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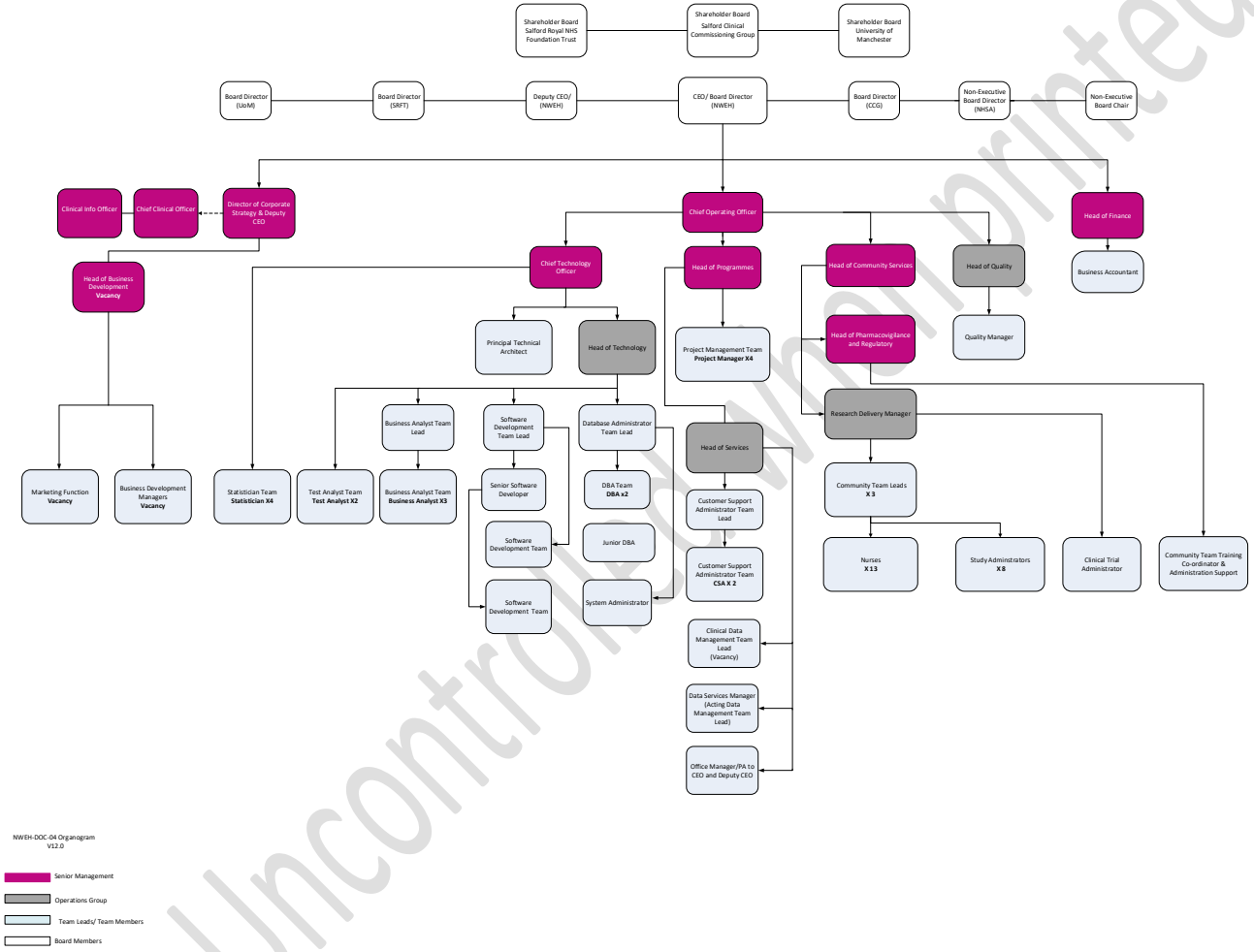
4) Our organisational structure

For current version see NWEH-DOC-004



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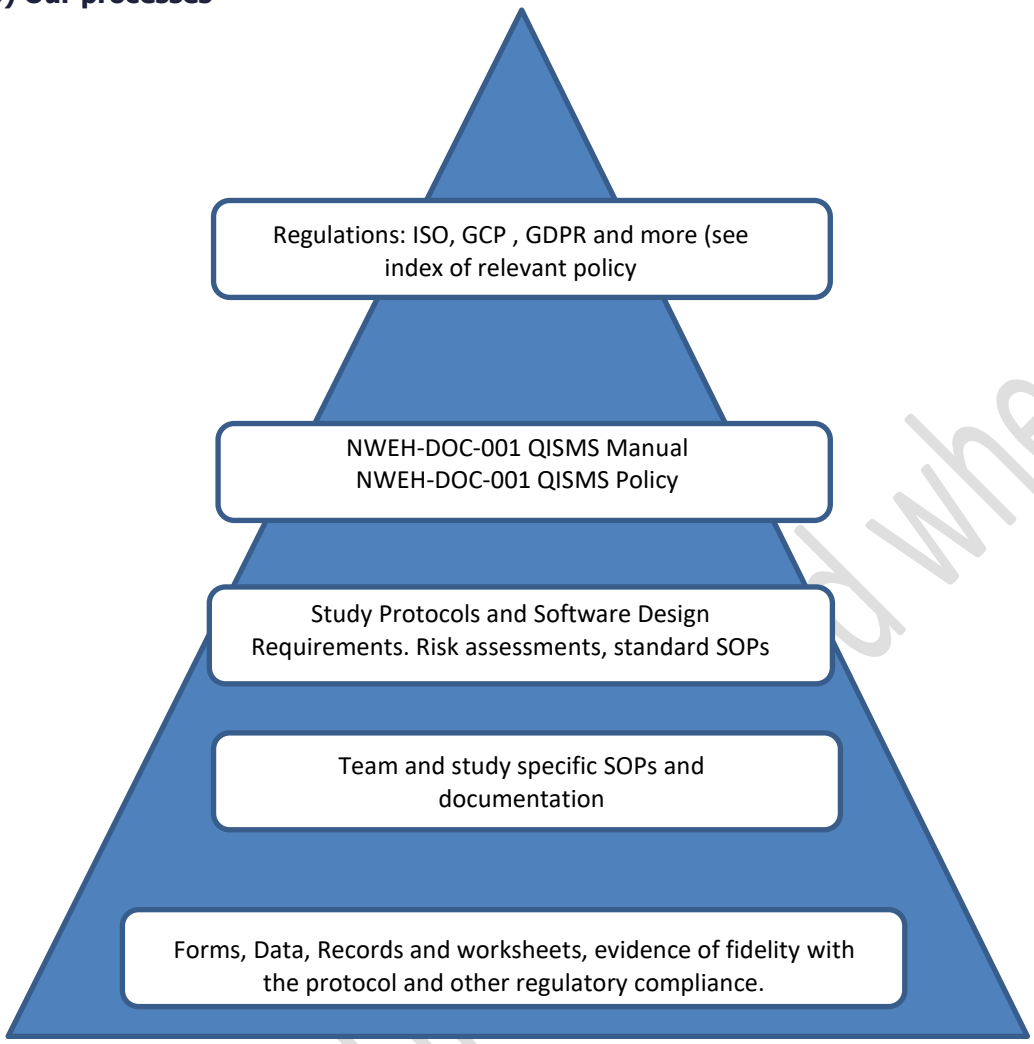
5) Our processes



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 a number of 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 the course of project delivery.

NWEH Project Managers use NWEH-DOC-076 Central RAID Log and the risk management procedure is documented in NWEH-SOP-068 Project Management. Any risks to our information assets are escalated via NWEH-DOC-006 Information Security Risk Log, which is closely monitored by our Senior Management Team.

A number of Standard Operating Procedures (SOPs), policies, and work instructions, which govern NWEH's key business activities, and 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 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 organisation, Salford Royal Foundation Trust.

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

The Quality and Information Security Management System, including:

Document Control

Internal Auditing

Non-conformity management

Management of information security risks

Software Development and Computer Systems Validation Processes

Clinical Operations including trial specific documentation and processes

HR

Supplier Management

QISMS risks, responsibilities and system scope

Project Management

Business Development

Approval

Name	Role	Signature	Date
Jo Macey Quality Manager	Author	DocuSigned by:  Signer Name: Jo Macey Signing Reason: I am the author of this document Signing Time: 12/3/2018 12:24:11 PM GMT 47C15D81F7FB47529817F5B3932F3AD8	03-Dec-2018 | 12:25 GMT
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