Innovation Quality Manual

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Innovation Quality Manual

1. Introduction

1.1 Description of the Innovation team

The West of Scotland (WoS) Innovation Hub (Innovation team) is a collaboration between Research & Innovation (R&I) and eHealth in NHS GG&C with a hub and spoke support model operating across the WoS Health Boards. The innovation team support innovation projects from the early discovery stage through to late stage evaluation to meet regulatory requirements, with the longer-term aim of procurement for national adoption.

The Innovation team is therefore required to:

- meet governance and contracting requirements for all stages of the innovation life cycle
- develop an appropriate Quality Management System to Sponsor Clinical Investigations of novel medical devices developed in collaboration with the manufacturer, to ensure a safe and rigorous evaluation of the innovation product.

Many of the devices developed will be data driven algorithms resulting from digital innovation of clinical services. These projects require close partnership working with the eHealth members of the innovation team as well as Data Protection and Data Security Compliance within NHS GG&C. The innovation team is required to ensure appropriate governance of all research being conducted [mainly Clinical Investigations of non-UKCA marked Medical Devices (CIMD), Clinical Evaluation of SaMD or a performance evaluation of an IVD] and that work is conducted to an appropriate quality standard (see below). This remit extends to all research performed that involves patients, their tissues and/or their information as well as research involving Health Board staff and resources. Individual projects are reviewed for scientific content and quality, assessed for risk to patients, institutions and investigators, supported as appropriate to study funding and managed through to a successful conclusion.

In some instances, the innovation team will evaluate medical devices developed by NHS GG&C that will be introduced under the Health Institution exemption and ISO 13485 and as such will not be placed on the open market. Similarly ISO 15189 accreditation underpins confidence in the quality of medical laboratories through a process that verifies their integrity, impartiality and competence. Assessments under UKAS accreditation ensure labs meet the relevant requirements including the operation of a quality management system and the ability to demonstrate that specific activities are performed within the criteria set out in the relevant standard. Some tests will be developed under UKAS accreditation – but not placed on the open market.

1.2 Background to the regulation of medical devices and applicable standards

The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical devices market. Medical devices are split into 4 main categories:

- Software as a medical device (SaMD - defined as *a set of instructions that processes input data and creates output data)*
- General medical devices
- Active implantable medical devices
- In vitro diagnostic (IVD) medical devices

The current framework for medical devices in the UK is set out in the Medical Devices Regulation 2002, which implemented the EU Medical Devices Directives. However, the EU regime has been significantly updated by the Medical Devices Regulations 2017/745 which aim to improve the safety of medical devices, including post marketing surveillance. These regulations have been applicable in the EU since May 2021 but do not apply in Great Britain and have not been implemented into UK law. Post Brexit, transition arrangements apply for devices with a current CE marking (valid till end June 2023). The MHRA hopes to have a new regulatory regime in place by this date. This is likely to be aligned closely to the EU regulations.

The UK Conformity Assessed (UKCA) marking is a UK product marking used for medical devices being placed on the Great Britain market (England, Wales and Scotland). Conformity assessment must now be conducted by an Approved Body in UK (Notified Body elsewhere in Europe). This requires assessment of compliance versus regulatory requirements for the category of device being certified. However, manufacturers of non-sterile and non-measuring Class I devices and general IVDs can self-certify against the UKCA marking.

UKCA marking requirements are based on the requirements of the relevant Annexes to the Directives listed below, which have been modified by Schedule 2A to the UK MDR 2002:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

1.3 Aims and Objectives of the West of Scotland Innovation Hub

The West of Scotland Innovation Hub is funded by the Chief Scientist Office, Scottish Government through an annual service level agreement (SLA) which specifies the key objectives that need to be met and the functions that need to be delivered.

Objectives:

- To support additional capacity in NHS Boards, IJB's and associated regional and national groupings to undertake projects that enable partner organisations to innovate.
- Funding is to be used for projects that are aligned to the clinical priorities of NHS Scotland as defined by the Health and Social Care Management Board, and those identified in the Demand Signalling plan published by the Scottish Health and Industry Partnership, on behalf of the Scottish Government.
- Funding is also to be used to support Catalyst competitions that are launched through the Scottish Health and Industry Partnership.

Functions:

- To provide opportunities for accredited external organisations to work with NHS and Social Care professionals on projects in real world settings.
- Register all projects via the PCS Innovation Portal / Scotland Innovates as appropriate.
- Respond to relevant innovation projects / opportunities that are registered via the Scotland Innovates portal, in line with an agreed process.
- To work in accordance with guidance from the CSO in Scottish Government and relevant governance structures in place.
- To support working with the Innovation Centres and Digital Health & Care Innovation Centre.
- Produce an annual Innovation Plan to capture local, regional and national priority actions. This will build on existing innovation plans, front line staff ideas generation platforms, Innovation Hubs, Academic Health Science Networks and other initiatives.
- Produce an Annual Review, in line with a template designed in cooperation with the Scottish Health and Industry Partnership, to monitor the impact of funding against outcomes.
- Ensure that support is available for Catalyst funded competitions.

- Apply for local and national project funds to solve priority clinical needs and those areas identified for NHS Scotland in the Demand Signalling Plan.
- Participate in national Open Innovation initiatives such as SBRI competitions supplying Test Bed access, support and advice to industry.
- Accept referrals for and provide advice and feedback to Health Innovation Partnership advice from the NHS NSS Innovation Hub.
- Offer evaluation of ideas, products and services as part of a national Test Bed in conjunction with national advisors from NHS HIS (Scottish Health Technology Group) NHS NSS, national networks and experts.
- Provide Reference site access as part of any separately funded Industrial Innovation initiative.
- Support local and regional health and social care systems for the adoption of proven innovations, inclusive of products and services identified as priority innovations by the Accelerated National Innovation Adoption Framework hosted by the Centre for Sustainable Delivery.

2 Scope of the Quality Manual

This Quality Manual is an extension of the overarching R&I Quality Manual (QM-RI-1) and works in cooperation with the content of the R&I manual. This Innovation Quality Manual applies to all staff and investigators working within the West of Scotland Innovation Hub. 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.

3. Definitions

Abbreviation	Definition
CAPA	Corrective and Preventative Actions
CSO	Chief Scientist Office
CSV	Computer Software Validation
CTA	Clinical Trial Agreement
GCRF	Glasgow Clinical Research Facility
GCTU	Glasgow Clinical Trials Unit
GCP	Good Clinical Practice
IVD	In vitro diagnostic medical device
MHRA	Medicines and Healthcare Products Regulatory Agency
NSS	NHS National Services Scotland
RP	Responsible Person
R&I	Research and Innovation
RCB	Robertson Centre for Biostatistics
SaMD	Software as a medical device
SAS	Scottish Ambulance Service
SOP	Standard Operating Procedure
WI	Work Instructions
GUI	Guidelines
QMS	Quality Management System

4. Management Responsibility

The R&I Director, R&I Innovation Lead and/or Senior R&I Manager sit on the following committees:

Committee	R&I Director	Senior R&I Manager	R&I Innovation Lead
Glasgow Health Science Partnership Regulatory Affairs Group (GHSP RAG)	✓	✓	✓
Glasgow Health Science Partnership Delivery Group (GHSP DG)	✓	*Can deputise for R&I director*	*Can deputise for R&I director*
Glasgow Clinical Trials Unit Management Committee	✓	✓	×
R&I Senior Management Committee	✓	✓	✓

In addition, the West of Scotland Innovation Hub have many committees at which Innovation projects are discussed and/or reviewed.

4.1 Innovation Management Committees

Title	Remit	Members
NHS GG&C Innovation Governance Group (IGG)	The NHS Greater Glasgow and Clyde Innovation Governance Group meet on a bimonthly basis to review and discuss new Innovation projects and agreeing their go ahead.	• Director of eHealth (Co-Chair) • R&I Director (Co-Chair) • Senior Innovation Administrator (Minutes) • eHealth Innovation Programme Director • Programme Specific Managers/leads • SiP Programme Manager • Innovation Clinical Leads • Head of R&I Finance • WoS Innovation Programme Manager • Director of Pharmacy • Deputy Medical Director, Corporate • GP IT Advisor eHealth • Information Governance Manager • Consultant and clinical lead eHealth • Head of Planning • Head of Medical Device Unit • Senior Communications Officer

WoS Programme Meeting	The West of Scotland Programme Meeting – monthly meeting to discuss ongoing projects, give updates and discuss any issues.	• WoS Innovation Programme Manager (Chair) • Senior Innovation Administrator (minutes) • eHealth Innovations Technical Lead • eHealth Applications Architecture Manager • Programme Specific Managers/Leads • Industry Collaboration Project Manager(s) • Senior Business Analyst/Project Lead(s) • Innovation Contracts Manager • WoS Innovation Lead
WoS Innovation Team meeting	The West of Scotland Innovation team's meet on a weekly basis to discuss new projects and bring any queries or issues to the group for discussion and agreement of ways forward.	• WoS Innovation Programme Manager (Chair) • Senior Innovation Administrator (minutes) • WoS Innovation Lead • Innovation Clinical Lead • Innovation Paeds Clinical Lead • Senior Communications Officer • Innovation Contracts Manager • Industry Collaboration Project Manager(s) • Senior Business Analyst/Project Lead(s) • Business Analyst/Project Lead(s) • Innovation Lead – NHS Forth Valley • eHealth Innovation Programme Manager • eHealth Innovation Programme Director • WoS Safe Haven Manager • WoS Safe Haven Project Manager

Sponsor Oversight – regulated trials only	To have oversight of NHS GGC Sponsored and co-Sponsored trials (CTIMPs and CIMDs) from proposal through to close out phases of the study. Also to have oversight of CTIMPs where NHS GGC have the Lead Site in the UK and/or has a central lab function. Frequency: Meet at least four times per year Terms of reference available	• Research Governance Manager (Chair) • R&I Director • Research Audit Facilitator • Pharmacovigilance and Safety Manager • Lead Pharmacist – Clinical Trials • Senior Clinical Trials Pharmacist • Lead Clinical Trial Monitor • R&I Quality Assurance Manager • Research Co-ordinator(s) • Innovation Contracts Manager • R&I Innovation Lead • Head of Research Regulation and Compliance (Glasgow University) • R&I Systems Manager • Senior Clinical Research Project Manager • Senior R&I Manager • Project Manager(s) • Director of Information Systems (RCB Glasgow University) • Quality Manager (Glasgow University)
National Project Management Support Group	Project managers across Scotland meeting to discuss SBRIs and any project issues. Sharing lessons learned and offering support to new project managers.	• Innovation Champion (NHS Lothian) • WoS Innovation Lead (NHS GG&C) • Industry Collaboration Project Managers (NHS GG&C) • Head of Digital Innovation (NHS Lothian) • Innovation Champion (NHS A&A) • Innovation and Improvement Lead (NSS) • Associate Director of RD&I (SAS) • National Improvement Advisor (Scottish Government) • Programme Manager for Innovation (Scottish Government) • WoS Innovation Programme Manager • Innovation Programme Lead (NHS Grampian) • Innovation Development Manager (NHS Tayside) • Innovation Project Team Manager (NHS Lothian) • Head of Communications and Engagement (SHIL) • Communications and Engagement Manager (SHIL) • Innovation Lead (CSO) • Innovation Lead – NHS Forth Valley • 'SHIP' representative • Senior Planner (Scottish Government)

The SHIP National Pipeline Group	Monthly meeting to discuss new projects coming through the SHIP pipeline	• Programme Lead for Open Innovation (SHIP) Chair • Programme Manager Industrial Collaboration (SHIP) • Programme Manager Industrial Collaboration (SHIP) • East Region Lead (HISES) • Innovation Lead NHS Lothian (HISES) • Programme Manager NHS Lothian (HISES) • West Region Clinical Lead (WoS) • Innovation Lead NHS Forth Valley (WoS) • Programme Manager (WoS) • Industry Collaboration PM (Wos) • Innovation Lead NHS Grampian (NoS) • Clinical Innovation Lead NHS Tayside (NoS) • R&I Manager NHS Highland (NoS) • Innovation Programme Lead NHS Grampian (NoS) • Head of Innovation CfSD NHS Scotland (ANIA) • Innovation Programme Manager CfSD NHS Scotland (ANIA) • Innovation and Improvement Programme Manager (NSS) • Commodity Manager (NSS) • Assistant Director of Finance DDOF NHS NWT| (Finance)
WoS Regional Innovation Governance Group (IGG)	The WoS Regional Innovation Governance Group meet on a bimonthly basis to review and discuss new Innovation projects and agreeing their go ahead.	• WoS Innovation Programme Manager (Chair) • Senior Innovation Administrator (minutes) • WoS Innovation Lead • Innovation Clinical Lead • Innovation Paeds Clinical Lead • R&I Director • Innovation Lead – NHS Lanarkshire • Innovation Lead – Golden Jubilee National Hospital • Innovation Lead – NHS Ayrshire and Arran • Innovation Lead – NHS Forth Valley • Head of Acute Services Planning and Redesign (NHS GG&C) • eHealth Innovation Programme Director • eHealth Innovation Programme Manager

Senior Management Team (SMT) – WoS Innovation Hub Meeting	The Innovation Team senior managers meet on a monthly basis to discuss any team or project issues at a managerial level	• Innovation Clinical Lead • WoS Innovation Lead • Innovation Paeds Clinical Lead • eHealth Innovation Programme Director
National Test Bed strategy committee	High level Innovation strategy group	• Head of CSO (Chair) • Regional Innovation Lead (s) (East of Scotland) • Innovation Clinical Lead (s) (West of Scotland) • Innovation Clinical Lead(s) (North Scotland) • Innovation Lead (CSO) • Innovation Lead (NHS GG&C) • Director of Delivery (Scottish Government) • Innovation Policy Lead (CSO)
R&I SOP committee	The R&I SOP committee meet on a quarterly basis to discuss the review of R&I standard operating procedures (SOPs)	• Representatives from each sub team across R&I, usually managers but a deputy can attend on manager's behalf

4.2 Management Review

The West of Scotland Innovation Hub Management Committees take responsibility for leading Innovation in the West of Scotland 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
- Stakeholder Feedback and Complaints
- Status of Deviation Reports and CAPA projects
- Recommendations for Improvement

All West of Scotland Innovation Hub staff have responsibility to report any areas of concern they have relating to the quality system to their line managers.

4.3 Resources

The Innovation Management Committees are committed to resource the quality management system to meet regulatory requirements and to maintain and improve the effectiveness of the quality management system and its processes.

4.3.1 Premises

The West of Scotland Innovation Hub 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.)

4.3.2 Staff

- The West of Scotland Innovation Hub 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.

4.3.3 Work environment

The West of Scotland Innovation Hub team shall determine and manage the work environment ensuring that the workspace is suitable for all West of Scotland Innovation Hub staff.

4.3.4 Organisational Chart

The organisational chart below (Figure 1) demonstrates reporting lines in the West of Scotland Innovation Hub, it is maintained by the Innovation Lead and updated as and when required.

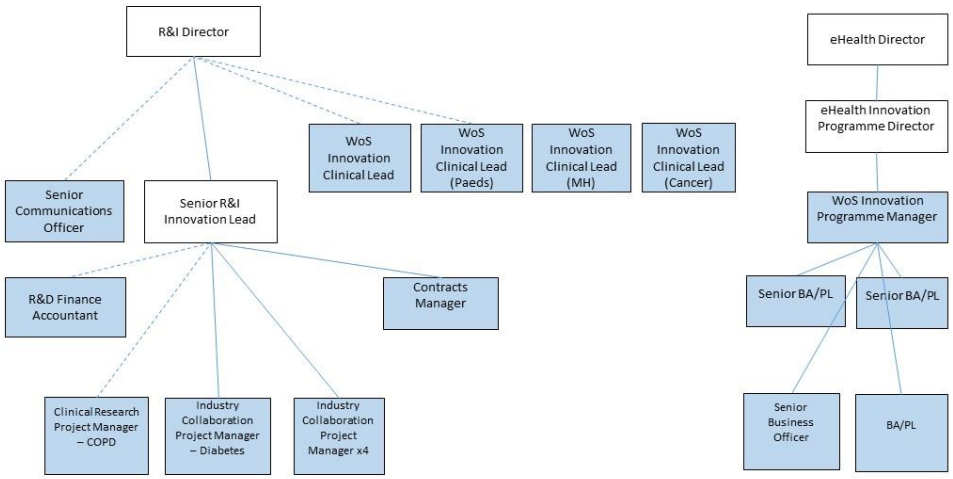

Figure 1 - Organisation Chart

5 Documents

The QMS includes the following documents:

- Quality Manual for the West of Scotland Innovation Hub, containing the Aims and Objectives..
- Documented standard operating procedures (SOPs) to ensure the effective planning, operation and control of West of Scotland Innovation Hub processes.
- Documented Forms associated to SOPs to capture required information for the completion of processes.
- Documented Guidance Documents (GUI) to detail how specified work should be carried out to ensure a systematic approach.

The West of Scotland Innovation Hub has an approved index of all SOPs and guidance documents governing its processes. All SOPs, Forms and Guidance documents are stored on the QMS (Q-Pulse), which maintains a master list of all SOPs, Forms and Guidelines and is managed by the R&I Quality Assurance Manager. This system can be accessed by West of Scotland Innovation Hub staff and contains all of the relevant information used for the management of these documents, the same documents are also made available through the Glasgow CTU website for ease of access to those external to R&I. The West of Scotland Innovation Hub takes ownership of preparing, amending and maintaining SOPs following SOP 50.023.

5.1 Document Control

The QMS has documented procedures (SOP 50.023 - Management of SOPs within NHS GG&C R&I) to control and manage processes associated with the operational and administrative procedures within the West of Scotland Innovation Hub. Procedures for the requirements of controlled documents more generally are also detailed within SOP 50.017 - Clinical Research & Innovation Document Management.

5.2 Change Control

A system is in place to ensure that the latest copies of all documents are available readily to ensure effective functioning of the West of Scotland Innovation Hub 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.

5.3 Retention of Records

Records relating to documents that comprise the QMS within Innovation are retained in Q-Pulse indefinitely in accordance with SOP 50.023. All records relating to the conduct of a trial are retained in accordance to the relevant archiving SOP 51.025.

6 Deviation Reporting and CAPA

The West of Scotland Innovation Hub 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 R&I Innovation Lead, Senior R&I Manager and Research Governance Manager. R&I have a process for the management of Non-Compliances which is detailed in SOP 51.008 and must be followed.

7 Risk Management

7.1 Risk Assessment Procedure

At the costing stage for all grant submissions or investigator-initiated projects developed in conjunction with industry, Form 51.010D will be completed and signed off to ensure that the regulatory position is understood at the outset and the project costed appropriately. In addition, West of Scotland Innovation Hub staff assess the level of risk for each Project. The risk assessment procedure is defined in SOP 51.004 using form 51.004A.

8 Training

The West of Scotland Innovation Hub ensures that all staff working as part of the West of Scotland Innovation Hub team are appropriately qualified and have received adequate training to enable them to carry out their duties and the duties delegated to them.

8.1 Staff Induction

Staff complete an induction, as per NHS GG&C standard policy, appropriate to their role, qualifications are checked and training needs assessed. Staff are provided with the list of SOPs and supporting documents that they must be trained in, as detail in SOP 50.023, before they can start work on their duties and projects.

8.2 Training File Maintenance

Individual staff are required to keep a training file that includes their CV, job description, training certificates etc. in line with SOP 50.013.

8.3 Training Competency

Each manager in the West of Scotland Innovation Hub is responsible for ensuring that training and resources are available to enable staff to be competent for their specified role.

8.4 Quality System Training

All staff are required to read and record the fact that they have read and understand the overarching R&I Quality Manual, this manual and the associated SOPs that relate to the Quality System specific to their role. This is controlled through the use of Q-Pulse as detailed in SOP 50.023.

8.5 GCP Training

GCP training is mandatory for all staff working in the West of Scotland Innovation Hub – this training must be refreshed every two years. Staff are responsible for ensuring that details of GCP and other essential training are recorded and certificates filed in their training record.

8.6 External personnel

Where relevant expertise is not available in-house the West of Scotland Innovation Hub employs out-sourced, external personnel to support its activities. The West of Scotland Innovation Hub also has external users. The West of Scotland Innovation Hub is responsible for ensuring that any external personnel working with/in the West of Scotland Innovation Hub comply with relevant regulations whilst working for the facility and complete West of Scotland Innovation Hub Induction Training.

8.7 UK GDPR

As the work conducted by the Innovation team involves the handling and management of data, the requirements of UK GDPR are built into all of the relevant processes within the team.

The Innovation team also work to SOP 61.005 which outlines the processes that need to be considered by Innovation when managing the design, review and approval of Innovation projects that require access to patient data.

An overarching Board Policy is also in place to address the requirements of UK GDPR which is followed by Innovation (Confidentiality and Data Protection Policy).

8.8 Incident Reporting (DATIX)

A board level process is in place for the reporting of Clinical and Non Clinical Incidents, DATIX. Incidents must be recorded through DATIX which is available to all staff through staffnet, the homepage of GG&C's intranet.

http://www.staffnet.ggc.scot.nhs.uk/

All incidents will then be reported to the appropriate manager in charge for further investigation and appropriate actions taken. This must take place alongside any processes undertaken to investigate issues within Research and Innovation.

8.9 Board Clinical Governance Forum

As Research and Innovation (including the Innovation team) sits within the Corporate Directorate of NHS Greater Glasgow and Clyde, Research & Innovation also report into Corporate Senior Management and the Board Clinical Governance Forum.

9 Audit

9.1 Internal Audits

- The West of Scotland Innovation Hub 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.

9.2 Internal Audit Report

- An internal audit report will be created to summarise audit findings in line with SOP 53.005.
- 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.
- 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.
- 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.

9.3 Third Party Audit/Monitoring Findings

- The West of Scotland Innovation Hub will support external audit/inspection and subsequent corrective and preventative actions.

9.4 Regular quality control (QC) checks

- All Innovation projects, including non-research projects will be added to SReDA. The R&I information officer will run monthly SReDA QC reports of newly active projects that don't have the 'SReDA updated by Research Administrator' ticked on SReDA and pass the report onto the relevant project managers to finish the data entry.
- The Innovation project managers will check the report and make sure their projects are fully up to date on SReDA (Scottish Research Database) in line with SOP 50.010 – Project Data Entry on SReDA and NRS ReDA 3 minimum dataset NRS-GUI-003.

10 Feedback from stakeholders

10.1 Complaints

- It is important that feedback from stakeholders is taken into account as part of the process for evaluating and continually improving the quality of the service provided by the West of Scotland Innovation Hub, refer to NHS Greater & Clyde Complaints Policy.
- Positive comments are reported back to staff and constructive feedback is used to improve our users' experiences.

10.2 Complaint Handling

The West of Scotland Innovation Hub follows NHS GG&C Complaints Policy for managing complaints. Formal complaints are directed to line manager in the first instance, who investigates the issue and attempts to resolve it as quickly as possible.

11 Vendor/Collaborator Assessment

When an innovation project has secured funding from an eligible funder the company/(ies) and collaborators will have undergone due diligence as part of the external review process. With investigator initiated projects no such review has been undertaken. With existing partner companies that have a track record of working with NHS GG&C, no further assessment will be required. However with new companies the assessment of vendors will be conducted to SOP 51.015.

12 Referenced documents

- NHS GG&C: Complaints Policy
- SOP 50.013: Setup and maintenance of training files: NHS
- SOP 50.017: Clinical Research & Innovation Document Management
- SOP 50.023: Management of SOPs within NHS GG&C R&I
- SOP 51.004: Risk Assessment
- SOP 51.005: R&I end of study procedures
- 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 51.010: Preparation and review of grant applications and costs
- SOP 51.015: Assessment of vendors
- SOP 51.025: Archiving Essential Documents from Clinical Research – Process for a Sponsored Non-CTIMP
- SOP 52.011: Quality Check of Project Entries on SReDA
- SOP 51.031: Corrective and Preventative Action Plan Management
- SOP 53.005: GCP Audit of Research Studies and Systems Supporting Research
- Form 50.010D: Grant or Investigator Initiated Study with a medical device – Checklist
- Form 51.004A Risk Assessment tool
- Form 51.010D: Grant with Potential non CA/CE marked Medical Device - Checklist
- ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- ISO 15189: 2012 Medical laboratories — Requirements for quality and competence
- The medical devices Regulations 2002
- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)
- The Research Governance Framework for Health and Social Care, 2nd Edition
- The Human Tissue Act 2004
- MHRA guidelines: 'Guidance on the maintenance of regulatory compliance in laboratories that perform the analysis or evaluation of clinical trial samples'
- EudraLex volume 4, Annex 1: EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use
- NHS Greater Glasgow & Clyde clinical and research governance provisions

13 Related documents

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