Health Research Institute (HRI)

Documentation Control Process

PURPOSE

The purpose of this process is to ensure that the correct version of documentation is available at all times. The procedure covers the review and control of all documentation in the Quality Management System. This includes:

- Key Business Processes
- QMS Processes
- Operational Procedures
- Quality Improvement Plan
- Forms / Templates / Work instructions
- Records

RESPONSIBILITY

The Operations Manager is responsible for this process.

PROCEDURE

All internally controlled QMS documentation is maintained in electronic format. The SharePoint electronic version is regarded as the master copy and is controlled using revision control, where required and with the guidance of the Quality Support Unit. All members of staff have access to SharePoint. Overall responsibility for publishing the general Quality Management System (QMS) documentation and that outlined below rests with the documentation controller- the HRI Projects Coordinator

- Key Business Processes
- Documentation Control Process
- Training and Development Process
- Communication Process

Once finalised on SharePoint the QMS documentation listed above is then published on the website according to the schedule outlined below.

Scope and Publication of QMS

The following table outlines the elements of the Quality Management System and where they are published.

QMS Document:	Published:
Key Business Processes	Web and SharePoint
QMS Processes	SharePoint
Operational Procedures	SharePoint
Forms/Templates/Work Instructions	SharePoint
Records	SharePoint
Quality Improvement Plan	SharePoint

Publishing Documentation

The procedure for publishing QMS content is as follows:

1. The requirement for a new process is discussed at unit-level meetings. A process owner is identified, and it is their responsibility to document the process and seek approval from the Head of Unit.
2. Change to an existing process is discussed with the process owner, either at unit-level meetings or following QMS audits.
3. The creation of the document or changes made to existing document.
4. Updating of the document and inclusion of brief details in the revision history tab, where required.
5. Approval for document new or amended) sought and achieved.
6. Document forwarded to the documentation controller (Projects Coordinator) for release.
7. The documentation controller (Projects Coordinator) publishes the document on the web and/or SharePoint and communicates the update to unit staff.

It is the responsibility of all staff to ensure that any paper material is the current version. Printed material is uncontrolled documentation.

Naming Convention

All documents are given a name relevant to their use. (Units decide whether to include revision number on document title).

Website Management

The HRI uses the website as a means of communicating with the key users of our services, with SharePoint being the primary means. Information is organised under relevant categories. The website has links to certain elements of our Quality Management System namely

- Key Business Processes
- Documentation Control Process
- Training and Development Process
- Communication Process

The website is hosted on an ITD server and is edited locally. The documentation controller (Projects Coordinator) or a delegate in their absence, is responsible for publishing the documentation outlined above on the website. HRI aims to review site content annually in conjunction with the QMS review process.to ensure it is current and relevant. All operational procedures (QMS Essential) are stored on SharePoint.

Review of Documentation

HRI carries out an annual process review co-ordinated by the Projects Co-Ordinator. The purpose of this review is three-fold:

1. To consider current unit-level procedures (individually and as a suite) in the context of continued relevance and fitness for purpose.
2. To identify any new procedures required.
3. To review all new University-level policies published over the previous year and assess their impact/relevance for unit-level procedures.

Revision Control

All relevant QMS documentation is given a revision control number, starting with revision 1 for 'Initial Release'. **This is conducted under the guidance of the Quality Support Unit.** The revision history**,** where used, is maintained at the end of each document. For forms, a revision date is sufficient. The aim is that **c**opies of old versions of documents are not normally maintained, once version control is being used.

RECORDS

Records are held by the HRI for the period defined by individual processes. All members of staff operate in accordance with the University's Records Management Policy Any personal data that is used as part of this process is processed in accordance with the General Data Protection Regulation (GDPR) / Data Protection Acts 1988-2018 and the University of Limerick's Data Protection Policy .

PROCESS VERIFICATION

Evaluation of process effectiveness is carried out using Internal/QMS audits.

REVISION HISTORY

Revision No.	Date	Approved by:	Details of Change	Process Owner
1	Sept. 2021		Initial Release	

2	Jan. 2024	Goretti Brady	PG1 Procedure • Added guidance from QMS Unit • Specified the QMS Documentation that the PM is responsible for the publishing. • Listed the QMS documentation ✓ Key Business Processes ✓ Documentation Control Processes ✓ Training and Development Process ✓ Communication Process PG 2 Website Management • Website changed from 'primary means' to 'means' of communicating. • Updated SharePoint as 'Primary means' of communicating. • Quality Management Systems (QMS) listed and linked. • Removed use of drupal as per instruction from ITD. • Site content changed to annual updates. • Referenced QMS storage on SharePoint. PG 3 Records Updated 'Records Management Policy' and 'Data protection Policy' All Pages Footer update to 'Rev 2'	Luan Lyons