

Memorandum of Understanding (MOU)

**Health Information and Quality Authority
and
Department of Health
and
Health Service Executive**

for

**A Public Engagement on the Collection, Use
and Sharing of Personal Health Information
in Ireland**

1. Introduction

The Health Information and Quality Authority (HIQA), having its head office at Unit 1301 City Gate, Mahon, Cork, Ireland and the Department of Health (the Department) having its head office at Block 1, Miesian Plaza, 50 – 58 Lower Baggot Street Dublin 2 and the Health Services Executive (HSE) having its head office at Dr. Steeven's Hospital, Dublin 8 ('the Parties') wish to establish a framework for cooperation and information sharing in areas of mutual responsibility and shared interest which fall within their respective statutory functions.

2. Interpretation

This MOU means the Clauses of, and the Appendices to, this MOU, all of which shall be read as one document.

3. Legal Mandate

3.1 HIQA, having been established under the Health Act 2007 (as amended) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public. HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children and Youth Affairs, HIQA has responsibility for:

- (a) **Setting standards for health and social care services** – Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- (b) **Regulating social care services** - The Chief Inspector of Social Services within HIQA is responsible for registering and inspecting residential services for older people, people with a disability and children's special care units.
- (c) **Regulating health services** - Regulating medical exposure to ionising radiation.

- (d) **Monitoring Services** – Monitoring the safety and quality of health services and children’s social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- (e) **Health Technology Assessment** - Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- (f) **Health Information** – Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland’s health and social care services.
- (g) **National Care Experience Programme** - Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of health and the HSE.

3.2 The Department, having been established under the Ministers and Secretaries Act 1924 - 2011, has an overall mission to improve the health and wellbeing of people in Ireland by delivering high quality health services and getting best value from health system resources. The Department's role is to provide strategic leadership for the health service and to ensure that government policies are translated into actions and implemented effectively. The Department supports the Minister and Ministers of State in their implementation of government policy and in discharging their governmental, parliamentary and departmental duties. This includes:

- leadership and policy direction for the health sector to improve health outcomes
- governance and performance oversight to ensure accountable and high quality services
- collaboration to achieve health priorities and contribute to wider social and economic goals
- an organisational environment where, on an ongoing basis, high performance is achieved, collaborative working is valued and the knowledge and skills of staff are developed

3.3 The HSE was established under the Health Act 2004 as the single body with statutory responsibility for the management and delivery of health and personal social services in Ireland. The objective of the HSE is to use the resources available to it in the most

beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public.

The HSE manage the health and social care services for the State as set out in the annual HSE National Service Plans (NSP). In line with the NSP and Slaintecare, the HSE is committed to providing safe, high quality health and social care within the limits of the available resources.

4. Purpose and Objectives

Purpose

- 4.1 The purpose of this MOU is to underpin a joint initiative by the Parties, in conjunction with patient representatives, to provide oversight, leadership and risk management to ensure the delivery of a public engagement on the collection, use and sharing of personal health information in Ireland. The public engagement will include a survey (the Survey) on opinions and attitudes relating to the collection, use and sharing of personal health information in Ireland. This MOU will provide a mechanism to assist cooperation between the Parties to ensure maximum effectiveness and efficiency when carrying out their respective functions and is intended to cover areas of common interest where cooperation will lead to improved services and better outcomes for people using those services. This MOU will set out roles and responsibilities of the Parties, the principles underpinning the interaction between the Parties and provide guidance on the exchange of information.
- 4.2 The Parties recognise that advances in eHealth and digital technologies, such as electronic health records and electronic patient summaries, have the potential to improve the quality of care provided to patients and also to promote organisational efficiency. The Slaintecare report published in May 2017, represents a new vision for the future of healthcare in Ireland. The Slaintecare Implementation Plan identifies that a modern health infrastructure in Ireland cannot be advanced without investment in eHealth and digital solutions.
- 4.3 This MOU takes note of areas of potential cooperation and collaboration between the Parties in relation to the advancement of the Slaintecare Implementation Plan and the improvement of ehealth and digital technologies for the benefit of health and social care service users in Ireland.

Objectives

- 4.4 The objectives of this MOU are as follows:
- (a) The Parties will work together and establish a partnership project team to conduct and deliver the public engagement on the collection, use and sharing of personal health information in Ireland.
 - (b) The Parties agree to establish a steering group for the purpose of the public engagement and have agreed terms of reference for the oversight and governance, membership and conduct of steering group meetings. The terms of reference for the steering group meetings are exhibited in Appendix 1 of this MOU.
 - (c) The Parties will ensure that the findings from the public engagement will inform improvements and changes in how health information is collected, used and shared in the Irish social and health care system.
 - (d) The Parties will ensure that the public engagement is developed and conducted with the involvement of patient representatives. The Steering Group has two patient representatives, from the HSE National Patient Forum and the Irish Platform for Patient Organisations, Science and Industry (IPPOSI). The role of the patient representatives is to ensure that the patient perspective is taken into account throughout the project.

5. Roles and Responsibilities of the Parties

- 5.1 The Parties agree that their respective statutory functions will be best discharged in the spirit of mutual cooperation and therefore agree to cooperate in particular in accordance with the agreed terms of reference for the conduct of the steering group which is established to ensure effective oversight, governance and risk management of the Public Engagement.
- 5.2 The Parties agree to establish and participate on a partnership project team which will support the operational requirements of the public engagement including but not limited to the development of the Survey.
- 5.3 The Parties agree, that in addition to clause 4.2 and 4.3 the roles and responsibilities of the Parties are as follows;

It is the role of HIQA to;

1. Assume the lead partner position for the purpose of the Survey, chair the steering group and provide an additional representative to be a member of the steering group
2. Provide the project team for the purpose of the Survey. The project team will be responsible for the development and delivery of the Survey, analysing and reporting on the Survey findings and developing the recommendations for a consent model for the collection, use and sharing of personal health information in Ireland
3. Publish the findings of the Survey, including a plain English report, on its website and develop an education and digital learning tool on the findings of the Survey and the benefits of the sharing of health information in Ireland
4. Develop recommendations for the Minister for Health on a consent model for the collection, use and sharing of personal Information in Ireland which will be informed by the findings of the public engagement

It is the role of the Department of Health to;

- Provide vision and leadership to ensure success of the Public Engagement
- Proactively use the findings of the Public Engagement to advance national policy and legislation on Irelands health information systems
- Provide two representatives for the purpose of membership of the steering group

It is the role of the HSE to;

- Provide vision and leadership to ensure success of the Public Engagement
- Proactively use the findings of the Public Engagement to advance national policy and legislation on Ireland's health information systems.
- Provide two representatives for the purpose of membership of the steering group

5.4 The Parties agree to share information in respect of the following matters:

Updates will be provided at steering group meetings, on the progress of the public engagement. This will include updates on:

- The project plan

- Methodology
- Recruitment of participants
- Public engagement findings (aggregate)
- Outputs

6. Confidentiality

- 6.1 The Parties will not use information disclosed under this MOU for any purpose other than the performance of their responsibilities under the MOU and in accordance with legislative requirements.
- 6.2 The Parties agree at all times to keep confidential, information that is expressed by either of the Parties to be confidential and shall use confidential information solely as is necessary for the performance of their responsibilities under this MOU.
- 6.3 The Parties agree to give notice to each of the other Parties of any unauthorised use, disclosure, theft or other loss of that the other Parties confidential information as soon as is practicable after becoming aware of it.
- 6.4 On termination of the MOU, the Parties agree to either return or destroy, any confidential information in tangible form which it possess, together with all copies and derivatives and extracts of any such confidential information.
- 6.5 Notwithstanding the above, if either of the Parties receives a request under the Freedom of Information Act 2014 to disclose any information that, is another Parties confidential information, it shall notify and consult with that Party who shall respond within 10 days after receiving the notice and provide information to assist the first Party to determine whether or not an exemption to the Freedom of Information Act 2014 applies to the information requested under that Act.
- 6.6 The Parties agree to do all acts and things as may reasonably be requested by any other Parties to the MOU with a view to compliance with legislation concerning privacy and data protection.
- 6.7 The Parties agree to comply with their obligations under Data Protection law at all times. The parties agree that no personal data will be shared by the Parties unless there is a lawful basis to do so.
- 6.8 Before transferring any information or personal data, each party will satisfy itself that any such transfer is not in breach of its own legislative provisions

regarding confidentiality and/or secrecy, or in breach of any other relevant statutory provisions, including the Data Protection Acts 1988 to 2018 and the General Data Protection Regulation 2016/679 (GDPR) and the Protected Disclosures Act 2014. Where information can usefully be anonymised before being transferred, each party will do so.

- 6.9 The Parties will ensure that any referral of information under the terms of this MOU is carried out in a manner that is prompt, efficient, proportionate and fully in compliance with the law.
- 6.10 Except as required or permitted by law, information shared between the Parties will not be provided to third parties without the written consent of the other Party. Any information or personal data disclosed by either party will not be used for any purpose other than the performance of the Parties statutory functions.
- 6.11 Any personal data shared between the Parties in furtherance of their responsibilities under this MOU shall be subject to a Data Sharing Agreement entered into between the Parties.

7. Financial Arrangements

Each party to the MOU will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under this MOU.

8. Variation

Any provision of this MOU may be amended at any time by mutual consent in writing of the Parties via the respective signatories to this MOU.

9. Status of Memorandum of Understanding

This MOU reflects the intentions of the Parties who will observe and give due respect to the agreed terms of the MOU. Each party acknowledges that this MOU is not intended to create any legally binding obligations of any nature. The Parties will observe and give due respect to the confidentiality undertakings expressed in Clause 5 of this MOU.

10. Effective Date

- 10.1 This MOU will come into effect upon the date of signature of all of the Parties and will continue in effect until its termination in accordance with clause 12.

11. Communication

- 11.1 All communications between the Parties pursuant to this MOU will be conducted on a formal basis through scheduled meetings of the steering group and where appropriate and on a less formal basis through the designated contact persons.
- 11.2 The designated contact persons responsible for the operation of this MOU are:

HIQA Contacts

The person holding the position of Director of Health Information and Standards

Department of Health Contacts

The person holding the position of Head of eHealth and Information Policy,
Department of Health

HSE Contacts

The person holding the position of Interim Chief Information Officer (CIO) of the
HSE

- 11.3 Upon signing this MOU, the Parties will ensure that the identity and contact details (email and telephone number) of the contact persons referred to above will be exchanged with the other party. In the event there is a change in the identity of a contact person referred to above during the term of this MOU, the relevant party will inform the other party of same and will forward the contact details of the replacement contact person.
- 11.4 All contact between the Parties pursuant to this MOU will be recorded by the designated contact persons outlined above.

12. Termination

- 12.1 The Parties may, at any time, give written notice of termination to the other Parties. This MOU will terminate one month after the date of receipt of the

notice of termination.

- 12.2 The termination of this MOU will not affect the confidentiality undertakings expressed by the Parties in this MOU or any commitments given under, or as a consequence of, this MOU in respect of any arrangements or action taken during the period before the termination takes effect.

13. Disputes

Any disagreement arising from the interpretation of this MOU will be referred to the Chief Executive Officer of HIQA, the Secretary General of the Department and the Director General of the HSE who will endeavor to resolve it within the spirit of this MOU.

14. Signatories

- 14.1. This MOU has been duly executed by the undersigned signatories on behalf of the Parties and each signatory represents and warrants to the Parties (other than that which he or she represents) that he or she has the authority to sign.
- 14.2. The Parties consent to the execution of this MOU by means of a [simple electronic signature] which shall be considered as an original signature and shall have the same validity, enforceability and permissibility as the original signature for the purpose of this MOU.

APPENDIX 1

Terms of Reference

Steering Group for the public engagement on the collection, use and sharing of personal health information.

1. Background

A major challenge for healthcare in Ireland today is striving to achieve an appropriate balance between the protection of personal health information, and the use and sharing of such information to improve care. Advances in eHealth and digital technologies, such as electronic health records and electronic patient summaries, have the potential to improve the quality of care provided to patients and also promote organisational efficiency. However, it is important to ensure that individuals are fully informed about the use of their data and that they have a good understanding of how, and by whom, it will be used. Every individual should feel confident that their personal data and information will be used and protected appropriately.

The complexity of Ireland's healthcare structures, with a predominantly paper-based system, makes the use and sharing of patient records difficult, particularly across organisations.

The Sláintecare Implementation Plan (Ireland's 10 year plan for healthcare) identifies that a modern health infrastructure in Ireland cannot be advanced without investment in eHealth and digital solutions. This will lead to greater availability of health information, improvements in decision making and ultimately safer care and better outcomes for patients. However, more clarity is needed around how a consent model for these digital solutions would work; the public should be able to trust that their personal health information is safe, and is used and shared appropriately in ways that are acceptable to them.

In Ireland, there is currently a lack of clarity around the consent model for the collection, use and sharing of personal health information. Some advances have been made with the introduction of General Data Protection Regulation (GDPR) and Health Research Regulations (2018). However, further clarity is needed to enable safe and efficient use of health information and to build the public's trust.

HIQA is currently developing recommendations on a consent model for the collection, use and sharing of health information in Ireland. As part of this work, an [international review](#) on consent models in place in other countries has been published. A key finding was that public engagement and building a culture of trust in relation to the collection, use and sharing of health information is extremely important when developing a consent model.

To inform and influence key decisions on these matters, it is essential to engage with the public at the earliest possible opportunity. Internationally, the successful introduction of new eHealth initiatives and digital technologies in healthcare has been informed by public engagement. Countries such as England and Australia have seen vast amounts of resources wasted due to the failure of new eHealth initiatives that were not accepted by the public.^(2,3) Lack of prior engagement with the public was seen as a major barrier to success in both of these instances. New Zealand and Canada have good examples of effective public engagement such as the Data Futures Partnership "[Our Data, Our Way](#)" initiative and Canada Health Infoway's "[Better Health Together](#)" workshop.

HIQA aims to leverage its extensive experience managing a suite of national surveys including the National Inpatient Experience Survey and the National Maternity Experience Survey to engage with, listen to and understand the experience of the people that use Ireland's health and social care services through undertaking a public engagement survey. This feedback will be a rich source of evidence, providing valuable insight to HIQA, the Department of Health and the HSE informing national policy, future developments in health technology and HIQA's recommendations.

2. Purpose

The Steering Group for the public engagement will provide oversight, leadership and risk management to help to ensure the delivery of the public engagement project. Their oversight and input will ensure that the findings from the public engagement will inform improvements and changes in how health information is collected, used and shared across the Irish health and social care system. The Steering Group is responsible for encouraging the use of the public engagement findings across health and social care services. The Steering Group is chaired by the Director of Health Information and Standards (HIQA) and comprises of representatives from the Department of Health, Health Information and Quality Authority, Health Service Executive and relevant Patient representative bodies.

3. Membership

Membership of the Steering group for the public engagement will be as follows:

- Director of Health information and Standards (HIQA) (Chair)
- Three representatives for the Department of Health
- One representatives for the Health Information and Quality Authority (HIQA)
- Two representatives for the Health Service Executive (HSE)
- Relevant Patient Representative(s)

In attendance:

- Additional subject experts may be seconded as required.

4. Quorum

The quorum for meeting of the Steering Group for the public engagement on the collection, use and sharing of personal health information will be three members, to include at least one representative from each partner organisation.

5. Meetings

There will be approximately 6 meetings held at key stages throughout the project, from July 2020 to July 2021, the proposed date for the first meeting is:

- Thursday 09 July 2020 at 12pm – meeting will be held online.

6. Minutes

A formal minute of all meetings, actions to be taken and decisions agreed will be recorded.

7. Decision Log

The Steering Group for the public engagement on the collection, use and sharing of personal health information is the formal decision making body for the public engagement. For this reason a log of all decisions made by the group will be maintained and reviewed at each meeting.

8. Distribution of papers for meeting

All materials to inform the meeting will be distributed at a minimum of 1 week before the meeting date.

9. Nominations

As the Steering Group for the public engagement on the collection, use and sharing of personal health information is the formal decision making body for this project, the members are representatives on behalf of their organisation, therefore nominated alternates are not appropriate, as it will limit the effectiveness of the Steering Group.

10. Approval of / Agreement

In the interests of meeting agreed timelines, approvals and agreements may be required via email. The item that was approved / agreed via email, will be ratified at subsequent meetings.

11. Remit

The Terms of Reference for the Steering Group for the public engagement on the collection, use and sharing of personal health information are as follows:

- Provide strategic direction for the public engagement including ensuring that the development of the project aligns with national policies, available resources, legislation and strategic direction of the Irish healthcare system.
- Provide an oversight role ensuring agreed milestones and timelines are met by all organisations and that the public engagement is compliant with all relevant governance and legislative requirements.
- Manage and resolve high level risks that may delay or prevent the delivery of defined objectives within agreed timelines
- Oversee and support the budget requirements for the public engagement.
- Ensure that each partner organisation is fulfilling their roles and responsibilities as outlined in the memorandum of understanding.
- Ensure appropriate supports and resources are in place for the project team to conduct the public engagement.
- Sign off on the scope of the public engagement, ensuring that it is aligned with international best practice.
- Approve the most appropriate model for the public engagement survey and ensure that it is aligned to international best practice and legislation.
- Determine and agree on the output of the public engagement.
- Agree a strategic approach to external communications of the public engagement outputs.

- Oversee, promote and encourage the use of the results to inform improvement and change across the Irish healthcare system.

SIGNED for and on behalf of the **Health Information and Quality Authority**



Signature: _____
Printed Name: Phelim Quinn
Position: Chief Executive Officer

Date: 29 October 2020

SIGNED for and on behalf of the **Department of Health**

Signature: 
Printed Name: NIALL SIÓBHÁIN
Position: HEAD OF eHEALTH

Date: 27/10/2020

SIGNED for and on behalf of the **Health Service Executive**

Signature: 
Printed Name: JIM THAYER
Position: 1/c 10

Date: 16/09/2020