



The **Regulation and  
Quality Improvement  
Authority**

**Legal Framework Document for purposes of facilitating a Review of  
Deceased Patients Records to be conducted by the Regulation  
Quality and Improvement Authority (RQIA) as part of a series of  
actions instigated by the Department following the recall of  
Neurology Patients in the Belfast Trust**

October 2020

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## 1. Introduction

1.1 This framework has been produced by the Regulation & Quality Improvement Authority (RQIA) for the purposes of setting out the basis upon which it seeks the cooperation and collaboration of all relevant HSC bodies in conducting a review (the Review) of the clinical records (the Deceased Records) of patients of Dr. Michael Watt, a Consultant Neurologist (the "Consultant") who have died during the 10 year period prior to May 2018 (Defined Period).

1.2 For the avoidance of doubt, the Review will also include a small number of patients who have died either side of the Defined Period. There are two reasons for this. Firstly to address the concerns of those families who made direct contact with RQIA following the announcement of the Review by the Permanent Secretary in May 2018 regarding their deceased relatives who had been patients of the Consultant but died before May 2008. Secondly, to ensure that the case of any patient who was called as part of the "live recall" but who died before they were able to take part in the recall or complete an assessment with another neurologist is raising concerns, is given due consideration.

1.3 The intended parties to this framework are the :-

- Health and Social Care Board;
- Business Services Organization;
- HSC Trusts;
- Public Health Agency (PHA);

collectively referred to as the HSC bodies as defined under section 1 (5) of the Health and Social Care Reform Act 2009.

1.4 Principles established for this framework are that of cooperation and collaboration.

## 2. Background

2.1 On 1 May 2018, Belfast Health and Social Care Trust (Belfast Trust) announced a recall of 2,500 patients in the context of concerns regarding the clinical practice of the Consultant.

2.2 The concerns were raised in late 2016 and early 2017 and were in relation to the care and treatment provided by the Consultant to a small number of patients. Belfast Trust advised that restrictions were imposed on specific areas of the Consultant's practice (under review from December 2016) and oversight arrangements had been put in place.

2.3 The Belfast Trust commenced an internal review process and subsequently arranged

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a wider independent review of the Consultant's practice by the Royal College of Physicians (RCP), London, in July 2017. Identified concerns, culminated in the Consultant ceasing all patient care and treatment from the summer of 2017, both in the HSC and the private sector in Northern Ireland.

- 2.4 Following receipt of the RCP, London Report in April 2018, and acting on its expert findings and recommendations, Belfast Trust commenced a recall of 2,500 patients under the active care of the Consultant in May 2018.
- 2.5 A number of patients under the care of the Consultant in the private sector were also recalled by the Ulster Independent Clinic and Hillsborough Private Clinic.
- 2.6 On 2 May 2018, the Permanent Secretary of the Department of Health (DoH) issued a statement on the patient recall, directing RQIA to undertake a review of the governance arrangements of outpatient services in the Belfast Trust, with a particular focus on Neurology and other high volume specialties. This review would then be extended as part of RQIA's established inspection programme to address outpatient services delivered by the four other HSC Trusts in Northern Ireland.
- 2.7 The Permanent Secretary's statement included an additional direction to RQIA to commission a "*review of the records of all patients or former patients of the Consultant Neurologist, who had died over the previous ten years*" (the "Review"). See Appendix 1.

### 3. Legal context

- 3.1 All HSC bodies are ultimately accountable to the DoH for the discharge of the statutory functions imposed upon them. The framework document produced by the DoH to meet the statutory requirement placed upon it by the Health and Social care (Reform) Act (NI) 2009 describes the roles and functions of the various HSC bodies and the systems that govern their relationship with each other and the DoH
- 3.2 In addition to the specific legislative basis which enables RQIA to conduct this Review, the purpose of this framework is, to where possible, reinforce cooperative and collaborative working between the HSC bodies by outlining the governance arrangements, roles and responsibilities between the RQIA and the other HSC bodies facilitating the Review by the provision of records.
- 3.3 Section 2 of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (Reform Act) sets out the general duty imposed upon the DoH in respect of health and social care.

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- 3.4 In explaining what is required to enable the promotion of an integrated system of health care, Section 2 (3) of the Reform Act particularizes a number of actions which will be required to be put in place to enable the DoH to fulfil its duty.

Of most relevance to the Review is:

Section 2(3) (g) which states:-

*“To secure the commissioning and development of programs and initiatives conducive to the improvement of the health and social well-being of, and the reduction of health inequalities between, people in Northern Ireland”;*

And, Section 2 (3) which states:-

*“facilitate the discharge by bodies to which Article 67 of the Order of 1972 applies of the duty to co-operate with one another for the purposes mentioned in that Article.”*

Article 67 of the Health and Personal Social Services (Northern Ireland) Order 1972 (1972 Order) states:-

*“In exercising their respective functions, health and social care bodies, district councils, the Education Authority, the Northern Ireland Library Authority, and the Northern Ireland Housing Executive ... shall co-operate with one another in order to secure and advance the health and social welfare of the people of Northern Ireland”.*

Section 3 of the Reform Act states:-

*“The Department may do anything else which is calculated to facilitate, or is conducive or incidental to, the discharge of that duty”.*

#### 4. RQIA and its Statutory Functions

- 4.1 RQIA was established under the Health and Personal Social Services (Quality Improvement and Regulation (NI) Order 2003 (2003 Order) as amended by the Reform Act.

- 4.2 RQIA' general duties are stated in Article 4 of the 2003 Order. Article 4 (2) states;

*“(2) The Regulation and Improvement Authority shall have the general duties of—*

*(a) keeping the Department informed about the provision of services and in particular about their availability and their quality; and*

*(b) encouraging improvement in the quality of services”*

- 4.3 Article 35(1) of the 2003 Order lists RQIA functions as

*“35.—(1) The Regulation and Improvement Authority shall have the following*

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*functions—*

*(a) the function of conducting reviews of, and making reports on, arrangements by statutory bodies for the purpose of monitoring and improving the quality of the health and personal social services for which they have responsibility;*

*(b) the function of carrying out investigations into, and making reports on, the management, provision or quality of the health and personal social services for which statutory bodies have responsibility;*

*(c) the function of conducting reviews of, and making reports on, the management, provision or quality of, or access to or availability of, particular types of health and personal social services for which statutory bodies or service providers have responsibility;*

*(d) the function of carrying out inspections of statutory bodies and service providers, and persons who provide or are to provide services for which such bodies or providers have responsibility, and making reports on the inspections; and*

*(e) such functions as may be prescribed relating to the management, provision or quality of, or access to or availability of, services for which prescribed statutory bodies or prescribed service providers have responsibility."*

4.4 As well as specific functions as set out above RQIA is also subject to any other directions which may be issued by the DoH

4.5 Article 6 (2) of the 2003 Order, states,

*"The Department may give directions to the Regulation and Improvement Authority with respect to the exercise of its functions and the Regulation and Improvement Authority must comply with them".*

4.6 In the event RQIA does not comply with directions issued by the DoH without reasonable excuse the DoH has the power to either discharge the functions itself or make arrangements for another body to discharge those functions on its behalf

4.7 Schedule 1 of the 2003 Order states,

*"Subject to any directions given by the Department, the Regulation and Improvement Authority may do anything which appears to it to be necessary or expedient for the purposes of or in connection with the exercise of its functions".*

4.8 RQIA believes it is necessary and expedient for the HSC bodies to agree to this Framework Document to enable commencement of this Review in accordance with the exercise of RQIA's statutory functions and in compliance with the direction given by DOH.

5. **Powers of Department of Health in absence of Assembly**

5.1. The direction referred to above at paragraph 2.7 and appended at Appendix 1 was issued at a time when no Minister was in office and in the absence of an Assembly and all preparatory work in respect of this Framework has been commenced during this period.

5.2 For the avoidance of doubt, the Departments (NI) Order 1999 states,

*"Subject to the provisions of this Order, any functions of a department may be exercised by*

*(a) the Minister; or*

*(b) a senior officer of the department".*

Mr. Richard Pengelly as Permanent Secretary is the Senior Officer.

5.3 Northern Ireland (Executive Formation and Exercise of Functions) Act 2018 establishes that the absence of Northern Ireland Ministers does not prevent a Senior Officer of a Northern Ireland department from exercising a function of the DoH during the period for forming an Executive, if the officer is satisfied that it is in the public interest to exercise the function during that period. Mr. Richard Pengelly as Permanent Secretary and senior officer of the DOH exercised the function of the DoH by determining that such the Review was necessary and Dr. Michael McBride as Chief Medical Officer issued the Direction to RQIA

5.4 The remainder of this document will set out how RQIA intends to achieve the exercise of its functions in respect of this Review.

6. **Establishing the Priorities**

6.1 This Review will be required to be conducted in a number of staged phases. The purpose of this Framework is to set the basis for phase 1 which is the planning and preparatory work for obtaining a data set for those deceased patients who will be included in the Review and then securing access to the Deceased Records

6.2. Two work streams have been identified to enable RQIA to complete phase 1-

6.2.1 Identify all patients, or former patients, of the Consultant who have died

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within the Defined Period (Establishing and Confirming the Data Set); and

6.2.2 Obtain access to the Deceased Records (Access to the Deceased Records). A request has been made to HSC Bodies and Independent Sector organizations that an appropriate affiliate for each work stream would be identified for the purposes of working in cooperation and collaboration with RQIA. (Appendix 2)

6.3 Before being able to commence work on the two work streams set out above, in the absence of regulations to enable application of the Health and Social Care (Control of Data Processing) Act (Northern Ireland) 2016 which will provide a statutory basis under which the duty of confidentiality may be set aside, it has been necessary to consider the following:-

- Data Protection Act 2018 (DPA) and General Data Protection Regulation (EU) 2016/679 (GDPR);
- Common Law Duty of Confidentiality;
- Human Rights Act 1998;
- Freedom of Information Act 2000;
- Department of Health Code of Practice on Protecting the Confidentiality of Service User Information , April 2019 (Code of Practice);
- General Medical Council's Guidance paper "Confidentiality: good practice in handling patient information"; and
- Access to Health Records (Northern Ireland) Order 1993;

## 7. **Establishing and Confirming the Data Set**

7.1 A Health and Care Number (H & C Number) is a unique number, assigned by BSO which uniquely identifies a patient within the HSC system in Northern Ireland. To enable RQIA to obtain the required information for the Establishing and Confirming the Data Set, disclosure and use to RQIA of the H & C Number will be required.

7.2 The information of each patient for whom an H & C number is generated, is retained by each HSC Trust within its Patient Administration System (PAS). This information is fed into a regional Data Warehouse where it is stored in a regionally consistent format.

7.3 Whilst it would be possible for RQIA to access anonymized, aggregated and pseudonymized data from the Data Warehouse through the BSO's Honest Broker Service, this would not be sufficient to allow for accuracy in identifying the appropriate patient cohort for inclusion in the Review. It is recognized that inaccuracies can occur in inputting of the data into PAS and also as different coding systems are used by the HSC Trusts it is recognized that errors can occur in the formatting of those codes into the regionally consistent format referred to at

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paragraph 7.2

7.4 For the purposes of identifying the appropriate patient cohort required as part of the “live patient recall”, extensive work has been undertaken by BSO with regard to extracting the data from PAS and filtering this information based on specified variables. Through a process of further filtering based on coding for those patients who have deceased, a “Data Universe” within the Data Warehouse has now been created comprising details of patients who have deceased within the Defined Period but are believed to have been patients or former patients of the Consultant.

7.5 It is intended that by signing up to this Framework Document the HSC bodies acknowledge and agree to the sharing with RQIA of the information comprising details of those deceased patients held within the Data Universe as referred to at paragraph 7. 4 above, to enable the commencement of the requests for access to Deceased Records.

#### 8. **Access to Deceased Records**

8.1 RQIA, in exercise of its functions, seeks to do so with proper control of corporate, clinical and social care governance with the cooperation and collaboration of the other HSC bodies.

8.2 In the Review, “Deceased Records” refers to all clinical records including but not limited to, hospital notes and records, GP note and records private patient records in both hard copy form and electronic form.

8.3 Identified sources for the Deceased Records include but are not limited to:-

- BSO on behalf of the HSCB as the body responsible for holding and retaining GP notes and records of deceased patients;
- Hospitals within each HSC Trust where neurology services have been provided;
- Independent Health Care providers in which the Consultant is known to have practiced as a Consultant Neurologist in private practice;
- GP electronic records;
- NI Picture Archiving and Communication System (NIPACS); and
- Laboratory information systems.

8.4. The Access to Health Records (Northern Ireland) Order 1993 (1993 Order) was introduced to enable individuals to request access to their own health records and also to request access to health records of other persons including deceased persons if acting in a prescribed capacity.

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8.5 RQIA's request for Access to Deceased Records for the purposes of this Review does not fall within the scope of the 1993 Order. Nor do the provisions of DPA 2018 and GDPR apply in respect of deceased persons.

## 9. Duty of Confidentiality

9.1 The confidential nature of a person's health information continues to apply after the death of that person. This is referred to as the common law duty of confidentiality which will be relevant to the Review of the Deceased Records.

9.3 The Patient Advisory Committee (PAC) in its publication of March 2017<sup>1</sup> reiterated this as part of its advice and guidance, both the Code of Practice and the General Medical Council's Guidance paper "Confidentiality: good practice in handling patient information"<sup>2</sup>.

9.4 The duty of confidentiality is not absolute. The Documents referred to above at paragraph 9.3 highlight that if there is an overriding public interest for disclosing of confidential information, there is a possible justification for any disclosure which would otherwise be a breach of confidentiality.

9.5 The proposed Review is unique in its nature, not only in terms of extent, but also it relates directly to a situation which has raised considerable patient, public and media concerns around the safety and quality of the Consultant's medical practice. In addition to this, given the direction issued by the DoH forms part of a wider examination of Neurology services provided to all persons within Northern Ireland, there exists an overriding public interest in the purpose to be served by the disclosure and use of the Deceased Records for the Review

9.6 Consideration has been given to the necessity of requiring the Deceased Records to be provided in full and without redaction in the first instance. RQIA does not consider it will be able to conduct this Review in an open and transparent manner without sight of all information in its full form to understand the totality of the circumstances of each individual case.

9.7 As stated at the paragraph 6.1 the Review will be conducted in phases involving a

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<sup>1</sup> An Advisory note prepared by the Privacy Advisory Committee (N.Ireland) (March 2017)  
<http://www.privacyadvisorycommittee.hscni.net/PAC%20Advice%20Note%20Patient%20Participation%20in%20Research%20in%20Primary%20Care%20March%202017.pdf>

<sup>2</sup> General Medical Council's Guidance paper "Confidentiality; good Practice in handling patient information"  
[https://www.gmcuk.org/static/documents/content/Confidentiality\\_good\\_practice\\_in\\_handling\\_patient\\_information\\_-\\_English\\_0417.pdf](https://www.gmcuk.org/static/documents/content/Confidentiality_good_practice_in_handling_patient_information_-_English_0417.pdf)

number of panels. It is anticipated that as the Review progresses, the Deceased Records are likely to be filtered accordingly so that only the most relevant and necessary information is being reviewed.

9.7 The reporting of outcomes identified from the Review will be in anonymized form.

10. **Declarations by deceased service users to withhold consent from disclosure.**

10.1 If a service user prior to their death has made a declaration that they wish to withhold their consent from disclosure of their records to either a particular family member or in general, generally it is the expectation and good practice that any HSC body who is the holder of that information will seek to uphold that declaration.

10.2 Due to the extent of records and information likely to be required to undertake the Review it is unlikely that each HSC body will have sufficient resource to undertake a review of each Deceased Records prior to disclosure to RQIA in order to identify such declarations.

10.3 The purpose for disclosure and use is one which has an overriding public interest, and is required to enable the discharge of a statutory function by RQIA which includes not only conducting reviews under Article 35 as referred to at paragraph 4.3 above, but also to comply with such directions as issues by the DoH as referred to at paragraph 4.5 above. When this is weighed against the likely harm or distress caused as a result of a disclosure being made in these circumstances, it is envisaged that such likely harm or distress will not be such as to outweigh the public interest.

10.4 In the event of any such declaration as referred to in this section is found within the Deceased Records, the actions which RQIA intend to take are set out within Operational Protocol No. 6

10.5 In the event of a breach which results in a claim or proceedings the HSC bodies and RQIA, working cooperatively, will seek to identify and apportion responsibility accordingly.

11. **Security, delivery and receipt of the Deceased Records.**

11.1 The measures/protocols which will be adopted to ensure the Deceased Records remain secure whilst in possession of RQIA are set out in Protocols, 3, 4, 5, 9 and 10 of the accompanying Operational Protocol (as appended to this framework) Any protocols/procedures which have been developed to date will be reviewed regularly and updated as this Review progresses

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11.2 It will be the responsibility of each HSC Body to ensure safe transport of hard copy Deceased Records upon request by RQIA. Request of Records will be conducted by way of a staged approach. The number of Records requested at any one time by RQIA will be an agreed number, manageable for both RQIA and each HSC Body. The HSC bodies will be responsible for both delivery and return of Deceased Records. Procedures for acknowledgement and receipt of Deceased Records will be agreed between the RQIA and HSC Bodies prior to commencement of this Review.

11.3 All Deceased Records will be scanned and held in a PDF format as set out in Operational Protocol No. 7. A specific and secure electronic drive has been acquired will be used for this purpose.

12. **Additional consideration for protection of confidentiality**

12.1 Staff

Any staff member employed by RQIA is required to ensure that all information either on paper or PC screens is confidential until invited to view. Access to information for the purposes of the Review will be limited to a core group of staff. Updated specific training in protection of personal data and confidentiality will be provided to this core group of staff.

12.2 Expert Panels

An Expert Panel will comprise at least 3 members. These will comprise persons outside of the HSC Bodies and RQIA. Confidentiality agreements will be entered into, together with Data Sharing Agreements. It is intended the members will be from a medical background and so will be bound by their own professional codes of practice

12.4 The Expert Panel will be provided with secured Laptop hardware to be used solely for the purpose of the Review and will be required to comply with RQIA policies and procedures relating to protection and handling of personal data and confidentiality.

13. **Ethical Advisor**

13.1 An appropriately appointed Ethical Advisor will also be appointed for the purposes of providing guidance and direction in accordance with best ethical standards for reviewing and considering a deceased patient's health information.

14. **Requests for Access under the 1993 Order**

14.1 As stated above, the request by RQIA for the Deceased Records does not fall within the scope of the 1993 Order.

14.2 It is likely however, that upon commencement of this Review, there will be an increase in queries by families enquiring if their deceased relatives are included in the review, and if so, potentially seeking access to those records.

14.3 Any of the obligations/duties which arise in respect of a "holder" of Records as defined by the 1993 Order will remain with the specific HSC body which ordinarily holds the Records

14.4 It will therefore be the decision of the particular HSC Body as holder of the Deceased Records, to determine whether; the person making the request meets the requirements set out under the 1993 Order, the extent of access, if any, to be provided, and how that access will be facilitated. Such decisions will be made in line with current procedures for requests made under the 1993 Order

14.5 If a request is made at a time when the Deceased Records are being held by RQIA then these records will be returned to the HSC Body as soon as is practicable. Operational protocol No. 12 sets out procedures for how such request will be dealt with.

15. **Family Engagement Personnel**

15.1 RQIA will be seeking input from specialist Family Engagement Personnel provide assistance in any communications with family members of the deceased.

15.2 In the event of any requests received by RQIA from a family member for access to their deceased relative's records, these will be reported to the Family Engagement Personnel who will contact the appropriate Affiliate appointed by each of the HSC bodies.

16. **Requests for Information – Freedom of Information Act 2000 (FOI Act)**

16.1 Any request to RQIA for information in respect of this Review which is made under the FOI Act will be processed in accordance with the requirement under the FOI Act All requests for information will be considered in full including consideration of any applicable exemptions.

16.2 Where RQIA is requested to provide any information in respect of the Records under the FOI Act, consultation with the relevant HSC Body or bodies will take place prior to the provision of any information.

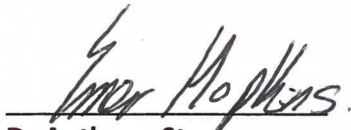
17. **Duty to Disclose**

17.1 RQIA will at all times seek to ensure that no information relating to the data and Records of any person is disclosed to any third party unless, as set out above, disclosure is required under the FOI Act, or by law, court or tribunal.

17.2 Notwithstanding paragraph 17.1 above, occasions may also arise whereby RQIA is required to disclose information in respect of the Review, in the vital interests of other persons or for reasons relating to the health, safety or welfare of other persons, for reasons of public health, for the purposes of any criminal investigation or to the Coroner. No such disclosure will occur unless and until the following:-

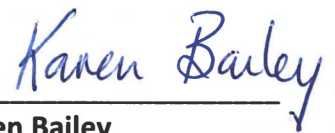
- The relevant HSC Body has been informed;
- Any legal advice required has been considered; and
- Agreement has been reached with regard to the extent of the Information required to be disclosed and if necessary, anonymized.

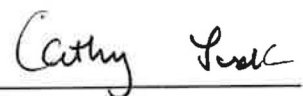
18. Signatories of HSC Bodies participating in this Review

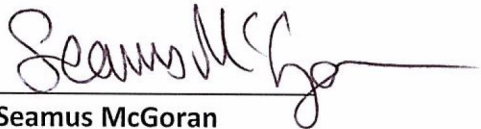
Signed  Dated 6-11-20  
**Dr Anthony Stevens**  
Interim Chief Executive Director of Improvement  
Regulation and Quality Improvement Authority

Signed  Dated 6 November 2020  
**Sharon Gallagher**  
Interim Chief Executive, Health and Social Care Board

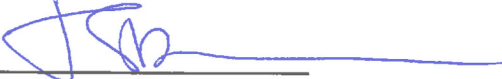
Signed  Dated 10 November 2020  
**Olive MacLeod**  
Interim Chief Executive  
Public Health Agency

Signed  Dated 27/11/20.  
**Karen Bailey**  
Chief Executive  
Business Services Organisation


Signed  Dated 9/11/2020.  
**Dr Cathy Jack**  
Chief Executive  
Belfast Health and Social Care Trust

Signed   
**Seamus McGoran**  
Interim Chief Executive  
South Eastern Health and Social Care Trust

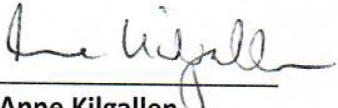
Dated 9.11.20

Signed   
**Shane Devlin**  
Chief Executive  
Southern Health and Social Care Trust

Dated 10/11/20

Signed   
**Jennifer Welsh**  
Chief Executive  
Northern Health and Social Care Trust

Dated 27/11/2020

Signed   
**Dr Anne Kilgallen**  
Chief Executive  
Western Health and Social Care Trust

Dated 18/11/20