



Ethical Framework to Inform Phase Three of the Expert Review of Records of Deceased Patients of Dr Watt

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Why is an ethical framework required?

The framework, which sets out principles to guide decision making, aims to ensure that Phase Three of the Expert Review is conducted in an open, transparent, sensitive and fair way.

How was this framework developed?

This Framework has been adapted from the Ethical Framework utilised for Phase Two of the Expert Review.

The Ethical Framework for Phase Two was developed by an Ethical Advisory Group (EAG) in partnership with the Project Team. The EAG consisted of individuals with relevant experience in the field of ethics, including via membership of bodies such as the HSC Clinical Ethics Forum and the Department of Health and Social Care's Moral and Ethical Advisory Group. The background to the Expert Review and the Terms of Reference for the Phase Two EAG can be found on the RQIA website¹. A series of 11 workshops were held to consider how established ethical principles could be embedded into the Expert Review; these culminated in the production of the Phase Two Ethical Framework.

The report on Phase Two of the Expert Review was published in November 2022. An independent evaluation was undertaken of the experience of Phase Two families; this provided valuable information on how families experienced the process and identified important learning for RQIA's engagement with further families. In Autumn 2023, RQIA engaged with further families who expressed an interest in becoming involved in Phase Three. The purpose of this engagement was to provide full information on the Expert Review's benefits and limitations, including alternative options available, to ensure informed consent. In July 2024, the Health Minister announced that a Phase Three would commence to examine the clinical records of a further 18 cases, where

¹ Ethical Advisory Group Terms of Reference, including pen bios:
<https://www.rqia.org.uk/RQIA/files/87/87b92be5-89fc-409a-b3a1-c3b417126ebd.pdf>

family members had approached RQIA with concerns about the care and treatment provided to their deceased relative.

During Phase Three the Framework was reviewed and adapted by members of Phase Three Expert Review Steering Group and Project Team. These comprise members who have experience in the fields of ethics, Human Rights, Patient and Public Involvement, governance, and lived experience.

How will this Framework inform decision making?

In conducting their work, Project Team, and third parties involved in the Expert Review are obliged to apply the principles outlined in this framework. Where specific ethical advice is required, RQIA will seek advice from a suitably qualified ethical advisor and / or group of ethical advisors.

The Ethical Framework was drafted in alignment with best practice principles in Human Rights and Information Governance.

With respect to any legal matters, although legal and ethical issues are often interrelated, this framework does not address legal matters. The Project Team has access to specific legal advisors to support this Review.

Where we commission third parties to undertake work, all parties involved will be asked to follow the ethical principles outlined in this Framework document.

Ethical Framework

Introduction

This framework sets out principles that the Project Team and third parties are obliged to apply when conducting their work.

The principles are not intended to be a rigid set of rules but will act as a guiding framework. They will be applied throughout Phase Three of the Expert Review, taking due account of context.

The principles are:

- Respect for Persons (which includes Privacy, Confidentiality and Data Protection, and the Right to Know and the Right Not to Know)
- Transparency and Candour
- Fairness
- Responsibility

Respect for Persons

Respect for persons involves treating individuals with dignity and respect; this applies both to deceased individuals and their family members. Respect for persons acknowledges that people should be treated as autonomous individuals, free to make their own decisions about how they want to participate in Phase Three of the Expert Review. In engaging with family members², the Project Team should respect the choices these persons make.

To promote respect for persons, the Project Team:

- Should ensure informed consent is obtained prior to participation in the Expert Review process.
- Should be thoughtful and consider when and how to engage with family members and demonstrate sensitivity to the cultural differences of persons involved in the Expert Review.
- Should ensure that the voice of the family members will be listened to and their contribution recorded and considered with the same significance as any other party contributing information to the Project Team.

² Including appointed representatives

- Should ensure psychological & bereavement support is in place for family members who wish to avail of it.
- Should support family members who lack the capacity to make decisions for themselves, to assist them in their decision-making in relation to this Expert Review.

i. Privacy, Confidentiality and Data Protection

Respect for persons also means respect for privacy and confidentiality.

Deceased patients are entitled to the same confidentiality as living patients with respect to their medical records.

To promote privacy, confidentiality and data protection, taking due account of legal requirements to disclose information in the public interest, the Project Team:

- Should be open and transparent about what organisations they share data with and why.
- Should ensure that all relevant data privacy policies and standards are observed and that data gathered during the Expert Review are used in a way that is limited to what is legally necessary³.
- Should respect and uphold requests they encounter within medical records where a patient, prior to death, has made a declaration that they wish to withhold consent from disclosure of their records to family members or in general.
- Should protect deceased individuals' and family members' identities by anonymising any published materials relating to this Expert Review.
- Should inform family members who are engaged with this Expert Review that they can withdraw their participation at any time without prejudice.

ii. The Right to Know and the Right Not to Know

The right to know and the right not to know is about ensuring people have the opportunity to decide the extent of information that is shared with them.

Family members may wish to exercise a right to know, or a right not to know, about Expert Review findings related to relatives who are deceased patients of Dr Watt. This information may relate to their own personal health and wellbeing. Family members

³ Legal Framework: <https://www.rqia.org.uk/RQIA/files/58/58d808ce-3c51-41a6-94d9-6edb9c0023f3.pdf>

will be supported in making informed decisions about the information shared with them.

To promote the right to know and right not to know, the Project Team:

- Should engage with family members to understand the extent of the information they wish to receive and be open and honest about the amount of information that can legally be shared.
- Should show respect by acknowledging that family members who are biological relatives may need to be informed about information that could impact their health. The Project Team will seek specific medical and ethical guidance in each individual circumstance.
- Should agree with family members what information they will receive and when.
- Should inform family members that there will be an option for them to receive a written summary of the assessment of the records at a later date.

Transparency and Candour

Transparency is being honest, open and visible about the decisions and actions taken and the reasons for those actions. Candour in healthcare is being actively open and honest with those involved when care has gone wrong⁴.

To promote transparency and candour, the Project Team:

- Should make publicly available as much information as possible and keep the public informed about the planning, progress and outcome of the Expert Review, so that, as required, action can be taken to enable and promote learning and improvement.
- Should be open and honest about the scope and resources available to the Expert Review, including what falls outside its remit.
- Should take into account the need to respect individuals, including their right to privacy and their right to choose not to be involved.

Fairness

Fairness is treating people in accordance with their needs and preferences, and without prejudice or discrimination.

⁴ [Duty of Candour \(professionalstandards.org.uk\)](https://professionalstandards.org.uk)

Inevitably not all records are going to be included in Phase Three of the Expert Review; differences in the timeliness in which records are reviewed requires clear explanation and justification⁵.

To promote fairness, the Project Team:

- Should make clear the reasons why some records are reviewed during Phase Three of the Expert Review, while others are not.
- Should ensure when reviewing deceased patients' records that the approach undertaken is without bias or preconception.
- Ensure that due consideration is given to individual accessibility needs and requirements, including ensuring that information is shared in a way that can be easily understood by individuals in accordance with their needs and preferences. Due consideration should be given to the needs of individuals with additional vulnerabilities, such as mental health conditions or cognitive impairment.

Responsibility

Responsibility is shown by fulfilling duties and being accountable for your actions.

This Expert Review is focussed on reviewing the records of selected deceased patients to identify any lessons. The Project Team should share this framework with all relevant parties and advise and offer guidance. The Project Team will be responsible for considering all findings, including responding to and, when appropriate, sharing information with other organisations.

To promote responsibility, the Project Team:

- Should use a rigorous and systematic approach in the Expert Review to achieve its objectives.
- Should share information with other organisations in a way that is appropriate and in line with public interest.

If family members or other relevant stakeholders are dissatisfied and wish to raise a concern or complaint about RQIA's approach to undertaking the Expert Review, this should be facilitated in the first instance through the RQIA Complaints Policy.

⁵ <https://www.legislation.gov.uk/ukpga/1998/47/section/75>

Details are available on RQIA website: [Regulation and Quality Improvement Authority - RQIA](#)

Other Ethical Issues Not Outlined In These Principles

Additional, specific ethical issues that are not encompassed within the framework may be encountered. In the event that any such issues arise, the Project Team will seek guidance from the EAG. If required, the Project Team will, as far as possible, seek consensus with the guidance of experts.

Any comments you may have on the content of this document and how it can be improved will be considered in future versions of the framework. Please send feedback to expert.review@rqia.org.uk