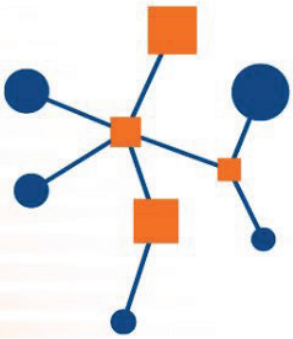

# BBMRI-ERIC®

The European research infrastructure for biobanking and biomolecular resources in health and life sciences

# EHDS Opt-out Position Paper 2025

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# OPT-OUT FROM SECONDARY USE UNDER THE EHDS REGULATION

## Recommendations from the viewpoint of Patient Advocates and Patient Representatives

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*The purpose of this position paper is to provide recommendations on the implementation of the opt-out process/mechanism for secondary use under EHDS regulation from the viewpoint of patient advocates and patient representatives.*

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## Introduction

European Health Data Space (EHDS) regulation guarantees citizens the right to opt out of the secondary use of their health data. The implementation of this right is subject to national law, but harmonised implementation is desirable. This statement summarises the recommendations and concerns of patient advocates and patient representatives regarding the implementation of the right to opt-out from secondary use of health data under Art.71 EHDS Regulation.

This position paper reflects the joint efforts of patient advocates and representatives from patient organisations which are members of the BBMRI-ERIC Stakeholder Forum – Patients and Citizens Pillar in collaboration with the BBMRI-ERIC team. The recommendations presented are solely from the perspective of patient advocates and patient representatives to the implementation of the right to opt-out from secondary use of health data as outlined in Art. 71 of the EHDS Regulation.

# Recommendations

## 1. Patients and citizens must be informed about the use of their health data for secondary purposes under EHDS regulation and their right to opt-out.

An opt-out mechanism is only effective if patients and citizens are well-informed, clearly guided, and reassured about the importance of their decision. Communication about use of their data for secondary use and their rights for opt-out must be hybrid, transparent, and empowering, ensuring patients understand both their rights and the value of their contribution.

- The most important step is to ensure all citizens and patients are **aware that their health data might be used for purposes laid down in the EHDS Regulation without prior individual information and of their right to opt-out** of secondary use of their health data.

- Information should be **transparent, easy to find,** and **clear** (lay language).

- Initial information should come from a **trusted first point of contact** in the healthcare system (general practitioners, nurses, or researchers) and should be complemented by other channels such as:
    - Online platforms and patient portals
    - Printed materials (important for elderly populations)
    - Public information campaigns

- The **content of the information is very important.** Patients and Citizens must be clearly informed about:
    - **What opt-out means** and how they can decide for what their data can be used for certain secondary purposes (multi-level mechanism of opt-out).
    - **Why their data matters** with realistic explanation of how health data contributes to research, innovation, and public health.
    - **Feedback mechanisms** of how their data has been used, to avoid the impression that it “disappears into a drawer.”
    - **Storage details**:
        - Where data is stored (location of secure servers)
        - What type of data is stored

  - How long data will be kept (clear retention periods, e.g., "X years after study ends" or "indefinite duration with safeguards", rather than vague terms like "minimum")
- The statement *"Building trust and showing respect towards patients is the first step"* is vital, timely information is therefore critical.

## 2. The opt-out system should go beyond a simple opt-out and allow for granularity. Patients and citizens want granular, flexible, and dynamic control over secondary use of their data.

- The **opt-out system should allow for a multi-level/tiered approach**, patients and citizens should be able to allow or refuse access to their data for secondary use depending on:
  - Purpose of use (e.g., research, innovation, education, health system etc.)
  - Data type (e.g., genomic vs non-genomic; sensitive vs routine data)
  - Type of actors (e.g., public research institutions, NGOs, industry, policy makers etc.)
  - Geography (e.g., inside EU vs international use)

- The **opt-out system should allow patients and citizens to change their decisions over time**: opt-out, opt back in, or adjust preferences.

- There should be **a post-mortem opt-out mechanism**. Patients and citizens should have the ability to specify whether their data can continue to be used after death, and whether their first-degree relatives can exercise opt-out rights on their behalf. This would respect both individual autonomy and familial considerations.

- Although flexibility of the opt-out system is important, options should remain clear and simple. A few broad categories (like purpose, type of data, and type of organisation) are better than many overly complex ones.

## 3. Secondary use of data obtained through consent should only be allowed if patients/citizens have re-consented or if the data is anonymised.

Especially for those data that have been collected on the basis of consent and would not exist without, **patients should always have the effective right to withdraw their consent and should**

**be informed if the data collected on the basis of consent would be used for secondary use under the EHDS regulation**. If re-consent cannot be obtained, data should be used for secondary use only if anonymised.

## 4. Declaring opt-out should be easily accessible, transparent and through multi-channel systems.

- Declaring opt-out should be made easily accessible, transparent and should be allowed through multi-channel systems (e.g., online portals, healthcare interactions, paper-based options), potentially supported by periodic reminders either through patient/information portals or during routine healthcare interactions. The focus should be on empowering patients and citizens to make informed choices throughout their care journey, without unnecessary complexity or risk.
- A central register of opt-out decisions may be useful for consistency, but only if designed in a GDPR-compliant way and would not contain fully identifiable data, only coded or pseudonymised references. The privacy of citizens and patients should always be guaranteed.

## 5. Trust and transparency are the key aspects in creating an opt-out system.

The focus should be on creating a system that is transparent and that informs the patients and citizens about their rights and creates trust. Generally, patients tend to be very open to providing their data for research, if they trust the system.

## 6. Opt-out systems should consider patients and citizens' needs. One-time investment in a transparent, fair and user-friendly system is desired and would be cost saving in the long run.

- **Opt-out systems should be designed to be simple, transparent, efficient, and cost-effective**, ensuring that administrative complexity does not create unnecessary costs for healthcare providers, researchers, patients and other stakeholders.
- It is important to highlight that the loss of opportunity for society due to potential loss of trust which would inevitably lead to refusal to share data for secondary purposes would be far greater that any current investment aiming to accommodate patients' needs. Therefore, one-time investment in a transparent, fair, and user-friendly system is justified and cost-saving in the long run.

## About the Stakeholder Forum

The BBMRI-ERIC Stakeholder Forum is the main interface for European patients' organisations, citizens, industry, and academia to interact with the biobanking universe. It is an integral part of BBMRI- ERIC's governance and culture. Through the Stakeholder Forum, we are building a sustainable, bidirectional relationship between the biobank community and its stakeholders. The objective is to increase each other's awareness of needs and expectations about key issues related to biobanking, such as data protection, informed consent in health research, health research priorities, secondary use of healthcare data, and other ethical, legal, and societal issues. Stakeholder Forum is enshrined in the BBMRI-ERIC Statutes and was put in place upon the inception of the BBMRI-ERIC in 2009 (read the report: https://www.bbmri-eric.eu/wp-content/uploads/stakeholders-forum-report-1.pdf).

The Stakeholder Forum is a place for active dialogue, sharing, two-way communications, delivering the views of stakeholders, and maintaining trust between stakeholders and the biobanking community. The Stakeholder Forum is structured into 3 pillars: (1) Patients and Citizens' Pillar, (2) Industry Pillar, (3) Scientific Pillar.

The Patients and Citizens' Pillar of the Stakeholder Forum currently includes 20 patient organisations from 14 Member States and 8 European-wide patient organisations. Patient organisations that have been actively involved in addressing biobanking issues have demonstrated a longstanding interest in BBMRI-ERIC and have made significant contributions to the advancement of this research infrastructure. The strategic aims of the Patients and Citizens' Pillar are grouped in three large themes: (i) Data & digital solutions: AI in biobanking, trusted research environments (commercial access), EHDS, tools to follow-up on the use of samples in research; (ii) Informed consent: automated consent, future of consent; (iii) Patients' involvement & engagement: involvement of patients and citizens in biobank oversight committees, research projects, ethics committees. All three themes support wider pan-European projects and initiatives, and all three reflect the interests and concerns of patients, citizens and patient organisations.


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Összefogás az egészségért, a mellrák ellen!
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