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Panel: Consent, Opt-Out and Data Governance in the EHDS

Beyond Individual Autonomy

Re-evaluating Consent and Open Data Obligations
in the EHDS Secondary Use Framework

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Data as Identity-Related Goods

Core thesis: Personal data are not economic assets — they are a numerical representation of identity. **Consent is not a contractual negotiation, but a condition of lawfulness for the exercise of an activity that is independently justified by public interest:** an authorisation that never transfers the underlying personality right.

Key Legal References

Art. 8 ECHR

“Everyone has the right to respect for his private and family life, his home and his correspondence.”

Arts. 7 & 8 EU Charter

Everyone has the right to respect for his or her private and family life, and to the protection of personal data.

The Analogy



Consent to organ donation as an exercise of self-determination over one's own body: the law predetermines its effects, and the individual cannot choose the recipient or negotiate a price.

Opt-Out as a Personality Right

Article 71 — EHDS Regulation

Individuals may, at any time and without providing any reason, refuse the processing of their personal electronic health data for secondary use. The exercise of this right is reversible and does not affect data permits issued before the opt-out was exercised.

1

Default Availability

Health data available for secondary use for public health, research, HTA, regulatory oversight

2

Revocable Permission

Not an affirmative contractual grant but a precarious concession, withdrawable at any time

3

Override Limits

Can be overridden only in narrowly defined circumstances of compelling public interest

The Data Holder as Fiduciary

The data holder does not acquire proprietary entitlement. **They are a manager in the interest of others** — a **fiduciary** collecting, organising, storing, and making data available.



Interest of the Individual

- Data protection safeguards
- Purpose limitation
- Data minimisation
- Opt-out mechanism (Art. 71)



Interest of the Collectivity

- Health data as common goods
- Public health & research
- Social progress
- Obligation to share with HDABs

Conclusions & Remedies

*Health data are identity-related goods and common goods at once.
Consent is a personality right, not a contractual transaction.*

Administrative Sanctions

Restorative & satisfactory function with respect to the public interest. Applied when data holders fail to share data, process outside permitted purposes, or disregard data permit conditions.

Tortious Liability

Violation of personality rights: re-identification attempts, use for prohibited purposes, failure to respect opt-out. Significant consequences on the burden of proof.

Thank you for your attention