Submission to EDPB Public Consultation

Guidelines 1/2026 – Processing of Personal Data for Scientific Research Purposes

1. AI-driven inference in genomic data, family networks, and the right not to know

The use of artificial intelligence in genomic medicine introduces new forms of **data inference and indirect identifiability** that extend beyond the original scope of data collection.

AI systems may:

- infer genetic relationships across datasets
- enable re-identification of relatives within family structures
- generate clinically relevant incidental findings affecting third parties
- produce derived health information not explicitly collected from the data subject

This raises significant implications under **GDPR Article 9(1)** (special categories of data, including genetic and health data), particularly where inferred data may qualify as personal data even if not directly provided by the data subject.

In family-based genomic contexts, a conflict may arise between:

- **Article 7 GDPR (consent)** of one family member for broader disclosure, and
- another individual's **right not to know**, as recognised in Article 10(2) Oviedo Convention.

AI-enabled inference may result in indirect exposure of health-relevant genetic information to individuals who have explicitly opted out of receiving such data.

Regulatory issue:

Whether current GDPR safeguards sufficiently address **indirect inference of sensitive genetic data through relational AI analysis**, including:

- inferred personal data under Recital 26 GDPR
- family-based data propagation effects
- and secondary disclosure pathways not explicitly covered by original consent

2. AI-mediated clinical decision-making and limits of disclosure control

In clinical practice, healthcare professionals function as intermediaries between complex medical information and patient comprehension, operationalising **informed consent under GDPR Article 6(1)(a) and Article 9(2)(a)**.

However, AI systems increasingly:

- generate multi-layered predictive outputs
- expand diagnostic and prognostic scope
- and produce probabilistic risk stratifications beyond human interpretability

This creates operational pressure on the physician's role as a disclosure intermediary.

Furthermore, it raises questions regarding the **therapeutic privilege doctrine**, traditionally allowing limited withholding of information under strict proportionality and clinical judgment.

In AI-assisted environments, two regulatory tensions emerge:

(1) Feasibility of informed mediation

Healthcare professionals may be unable to fully evaluate or contextualise all AI-generated outputs in real time, raising concerns regarding the practical implementation of:

- GDPR Article 5(1)(a) (fairness and transparency)
- Article 12–14 (information obligations)

(2) Algorithmic mediation of disclosure

AI systems may be used to prioritise or filter disclosure based on estimated psychological impact or behavioural prediction models.

Regulatory issue:

Whether the delegation of disclosure structuring to AI systems is compatible with:

- the principle of **data minimisation (Article 5(1)(c))**
- **purpose limitation (Article 5(1)(b))**
- and the requirement that consent be informed, specific, and freely given (Article 4(11), Article 7 GDPR)

3. Right not to know under conditions of AI-generated informational expansion

Article 10(2) of the Oviedo Convention establishes both:

- the right to receive health information, and
- the right not to be informed

In AI-driven healthcare environments, systems may generate:

- multi-dimensional predictive risk outputs
- continuous probabilistic health forecasts
- and dynamically updated health trajectories

This creates a structural asymmetry between:

- the volume and granularity of available information
- and the binary nature of informational choice under current legal frameworks

A further complexity arises when AI systems attempt to infer a data subject's informational preferences based on behavioural or medical data patterns.

Regulatory issue:

Whether the use of AI to infer informational preferences is compatible with:

- GDPR Article 22 (automated individual decision-making and profiling)
- Article 9 (processing of health data and inferred sensitive data)
- and the principle of **purpose limitation under Article 5(1)(b)**

Particularly, whether the right not to know can remain effective in environments where sensitive health inferences may be continuously generated, even if not explicitly requested.

4. Hypothetical consent and limits of predictive modelling under AI systems

Certain legal traditions (notably German-speaking jurisdictions) recognise **hypothetical consent**, whereby consent may be assumed if a patient would have agreed under proper disclosure.

However, jurisprudence (e.g. Swiss Federal Supreme Court case law, BGE 117 Ib 197) emphasises that such assumptions must be grounded in the **individual circumstances of the patient**, not abstract statistical inference.

AI systems may attempt to:

- predict patient decisions
- model consent probabilities
- infer risk tolerance
- and reconstruct likely choices based on behavioural datasets

However, such systems operate within inherent limitations:

- reliance on observable data
- inability to capture non-quantifiable preferences
- exclusion of subjective, existential, or identity-based factors

Regulatory issue:

Whether AI-based predictive consent modelling can be considered compatible with:

- GDPR Article 22 (profiling and automated decision-making)
- Article 9(2)(a) (explicit consent for health data processing)
- and the requirement of genuine autonomy underlying informed consent principles

Particularly, whether reconstructing consent ex post via algorithmic inference risks undermining the legal integrity of consent as a **contextual and individual legal act**.

Overall conclusion

Across genomic inference, clinical decision support, and predictive consent modelling, a consistent structural issue emerges:

AI systems increasingly transform health data processing from direct observation into **multi-layered inference systems**, generating:

- derived personal data
- relational health insights
- and probabilistic behavioural predictions

This evolution challenges the current GDPR architecture, particularly regarding:

- inferred sensitive data (Article 9)
- transparency and informational rights (Articles 12–14)
- automated decision-making and profiling (Article 22)
- and the legal robustness of consent (Articles 4(11), 6, 7)

A potential clarification of the regulatory boundaries surrounding **AI-mediated inference in healthcare contexts** may therefore be warranted.