COMMENTS TO EDPB GUIDELINES 1/2026 – SCIENTIFIC RESEARCH

1. Scope and definition of scientific research

We welcome the effort to clarify the notion of scientific research. However, the introduction of six cumulative "key-indicative factors" may unintentionally narrow the concept.

- Industrial research, innovation activities, and AI-driven data analysis may not always fulfil all criteria (e.g. publication, independence).
- This creates **legal uncertainty for private sector research**, particularly in health technologies.

Recommendation: Clarify that **not all factors must be strictly met** and explicitly recognise **industry-led and innovation-driven research** as scientific research.

2. Presumption of compatibility (Art. 5(1)(b))

We strongly support the confirmation that further processing for scientific research is presumed compatible.

Recommendation:

- Reinforce that this presumption should apply broadly, including cross-sector and cross-border research.
- Provide practical examples for reuse of health data and real-world evidence.

3. Legal bases – legitimate interest and public interest

We welcome the recognition that:

- Scientific research can rely on legitimate interest
- Private entities may rely on public interest where supported by law

Concern: Lack of harmonisation across Member States may limit practical usability.

Recommendation: Promote **harmonised interpretation across the EU**, especially for health research and innovation ecosystems.

4. Consent (broad and dynamic)

We support the acceptance of broad consent.

Concern: The level of safeguards required may be **disproportionate and operationally burdensome**, especially for:

  - multi-centre studies
  - long-term research infrastructures

Recommendation:

- Introduce **proportionality criteria**
- Allow simplified models for low-risk research

5. Transparency obligations

The requirement for continuous information and updates is acknowledged.

Concern:

- May create **excessive operational burden**
- Risk of "information fatigue" for data subjects

Recommendation:

- Allow **layered and risk-based transparency models**
- Clarify when indirect information is sufficient

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6. Special categories of data
We support the flexible approach combining legal bases and safeguards.

Concern: Strong dependence on national laws creates fragmentation

Recommendation: Promote alignment with initiatives such as the **European Health Data Space (EHDS)**

7. Roles and responsibilities
We welcome the clarification on multi-actor environments.

Recommendation:
- Provide **standard models/templates** for:
  - joint controllership
  - public-private partnerships

8. Safeguards and proportionality
We agree safeguards are essential.

Concern: The guidelines may lead to **overly conservative interpretations**, limiting innovation

Recommendation:
- Emphasise **risk-based approach**
- Avoid one-size-fits-all requirements

Conclusion
The guidelines are a positive step towards enabling research while protecting fundamental rights. However, further clarification is needed to ensure they:
- Support innovation and industry-led research
- Avoid unnecessary administrative burden
- Promote harmonisation across the EU

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