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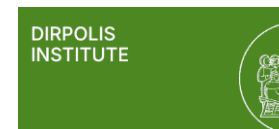
The legal framework to foster data driven-research

Il quadro normativo per promuovere la ricerca data-driven

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EU Reg. 2024/1689 & Research exemption

- Article 2(6) AI Act does **not apply** to:
AI systems developed **solely for scientific research and development**
- Key condition: Must remain within **research purposes only**



- Many tested AI systems may:
- Move beyond research settings
 - Be deployed operationally

Consequence: Providers must **comply with AI Act requirements by default**



EU Reg. 2024/1689 & Research exemption

- Exemption does **not excuse**:
 - Poor quality outcomes
 - Lack of accuracy
- **Research must still ensure**:
 - Scientific robustness
 - Reliable results



Even within research, is mandatory to:

- Assess **risk classification** of AI systems
- Analyse: Potential deployment scenarios & Future exploitation by investors



Recommended approach:

- Address requirements during **development stage**
- Document processes systematically
- Goal: Enable smooth transition to compliance



Research in Healthcare

AI Applies to public & private research organisations

Key provisions:

- Data processing = public interest basis
- No need for explicit patient consent

Flexibilities:

- General privacy notice allowed
- Secondary use of non-identifiable data permitted



Data Protection Mechanisms

- Processing of sensitive data:
 - Must be notified to Data Protection Authority
 - **Allowed unless** blocked within 30 days
- Support measures:
 - AGENAS guidance on:
 - Pseudonymisation
 - Anonymisation



Article 5 GDPR

Secondary use for scientific purposes of **personal data** is promoted under the article 5 GDPR, if the purpose is not incompatible with the one that based the primary collection of personal data.

It expressly presumes that scientific research purposes are compatible ones to enable secondary uses, under the conditions stated in article **89 GDPR**, including **technical** and **organizational safeguards** (eg **encryption** and **pseudonymisation**) to **protect data**.



Article 9 GDPR

§2, sub j) it establishes legal basis to process data belonging to special categories of data, under the conditions of article **89 GDPR**.

Article **89 GDPR** → Member States might introduce further safeguards under national law.

Limit to harmonization ... and to open science!





Reuse of data for research purposes in Italy

Before l. 56/2024 article 110

LD 196/2003 ss.mm.ii (Privacy Code)

Reuse of health-data for research purposes

- Consent of the data subject
- If not:
 - Ethical committee approval
&
 - A prior authorization of the data protection authority under article 36 GDPR



Current paradigm under article 110

Reuse of health-data for research purposes

- Consent of the data subject
- If not:
 - Ethical committee approval
 - Safeguards included in the general authorization of the DPA
 - To implement appropriate safeguards
 - To define why consent cannot be collected
 - To publish the DPIA





Comparative insights from Japan

Japan

- Mar 2025 Act on Advancing Responsible AI Research, Development and Utilisation
- Dec 2025 Guideline for Ensuring the Appropriateness of Research & Development and Utilization of Artificial Intelligence-Related Technology
- Apr 2026 APPI Amendments



- Principles to be applied through guidelines and soft law instruments
- Consideration for stakeholders based on the importance of data as the foundation of AI innovation
- Personal data for statistical analysis and AI development without individual consent, if pseudonymized, DPIA, purpose limitation





Conclusive remarks

Openness of research data increases the integrity and quality of results, through the opportunity to validate them by allowing other researchers **to reproduce experiments** and/or **replicate methodologies**, boosting innovation at the same time.

→ It is true also for AI systems!



Limits include:

- Data protection
 - Intellectual property rights
 - Commercial interest
 - Misuse
- New boundaries ... and opportunities within AI regulation!