



POLICY BRIEF

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LEGGE 132/2025:

DISPOSIZIONI E DELEGHE AL GOVERNO IN MATERIA
DI INTELLIGENZA ARTIFICIALE

ARIANNA ROSSI



The Italian law on artificial intelligence	
BACKGROUND AND FIELD OF APPLICATION	<p>On 17 September 2025, the Italian Senate definitively approved Bill No. 1146, titled “Provisions and Delegations to the Government on Artificial Intelligence”. The measure was subsequently published in the Official Gazette (Gazzetta Ufficiale No. 223) on 25 September 2025 as Law No. 132/2025. This legislation establishes Italy’s national regulatory framework for artificial intelligence (AI), designed to align with the European Union’s AI Act (Regulation (EU) 2024/1689). The law will enter into force on 10 October 2025.</p>
HIGHLIGHTS	<p>Article 3 sets foundational criteria for AI research, development, deployment, and use in Italy, without introducing obligations beyond those established by the EU AI Act:</p> <ul style="list-style-type: none">• Legal compliance: All AI-related activities must respect fundamental rights and freedoms guaranteed by the Italian Constitution and EU law.• Core principles: AI systems must adhere to transparency, proportionality, security, data protection, confidentiality, accuracy, non-discrimination, gender equality, and sustainability.• Data and process standards: Development must rely on correct, reliable, secure, high-quality, appropriate, and transparent data and processes, with safeguards proportionate to the application domain.• Human-centric design: AI must preserve human autonomy and decision-making, ensuring transparency, explainability, knowability, and human oversight.• Democratic integrity: AI systems must not interfere with democratic processes, institutional autonomy, public debate, or national sovereignty.• Cybersecurity requirements: Cybersecurity is mandated throughout the AI lifecycle, with risk-based controls to ensure resilience against manipulation.• Accessibility: The law guarantees full, equal, and non-discriminatory access to AI systems and functionalities for persons with disabilities. <p>Particularly relevant for BRIEF research activities are the provisions of Article 8 concerning health data used for developing AI systems:</p> <ul style="list-style-type: none">• Scope of application: Applies to data processed by public and private non-profit entities, IRCCS, and private actors engaged in



	<p>collaborative research with those actors for scientific and experimental purposes in the healthcare sector.</p> <ul style="list-style-type: none"> • Public interest: Data used for AI development in healthcare, including disease prevention, diagnosis, treatment, drug and therapy development, medical devices (e.g., prosthetics, body-interface tools), public health, safety, and studies of human physiology and biomechanics, is considered of public interest under Article 9(2)(g) GDPR. • Secondary use of personal data: Reuse of personal data without direct identifiers is always permitted, provided a public notice is published on the data controller's website (as per Article 13 GDPR). No additional consent is required if the original legal basis was established. • Permitted processing activities: Anonymization, pseudonymization, and data synthesis are always allowed. AGENAS will issue guidelines, subject to the opinion of the Italian Data Protection Authority. • Notification and safeguards: Processing may begin 30 days after notifying the Data Protection Authority, assuming no objections. The notification must include: <ul style="list-style-type: none"> ○ Technical and organizational measures (Art. 24 GDPR) ○ Data protection by design and by default (Art. 25 GDPR) ○ Security measures appropriate to the risk, including pseudonymization (Art. 32 GDPR) ○ Impact assessment (Art. 35 GDPR) ○ Identification of data processors (Art. 28 GDPR)
IMPACT	<p>The designation of public interest applied to health data is meant to simplify the use and reuse of such data for scientific purposes in the creation (<i>realizzazione</i>) of AI systems. Many complex provisions govern the reuse of health data (see Policy Brief 4 Update), which have hindered the advancement of scientific discoveries in this sector, and left scientists and practitioners devoid of legal and usable mechanisms to enable them.</p> <p>Article 9 delegated the Ministry of Health to issue an implementing decree to regulate health data processing, especially secondary use, for AI and machine learning research within 120 days of the law's publication. The decree will support the creation of dedicated experimentation spaces. The regulation process will involve consultation with the Data Protection Authority, research institutions, healthcare providers, and relevant stakeholders. It is expected that the decree will further clarify and simplify the reuse of health data for AI applications in the research sector.</p>