

COUNTRY: ITALY

Theme/ question:	Under the Directive + National Law	Under the GDPR + National law
<b>Legislation</b>	<b><u>Data Protection Code - Legislative Decree no. 196/2003</u></b>	The new legislative decree has yet to be adopted.
<b>Legal grounds applicable to scientific research purposes</b>	Health data could be processed based on consent and for scientific research purposes.	Health data can be processed based on consent and for scientific research purposes.
<b>Safeguards required - Conditions framing the processing of health data for scientific research purposes</b>	<ul style="list-style-type: none"> <li>- Compliance with the code of conduct</li> <li>- Notification to Data Protection Authority</li> <li>- Private entities could process sensitive data for scientific research purpose if there was a consent in writing and an authorisation of the Data Processing Authority (specific or general)</li> <li>- If information of the data subjects was not possible, an authorisation of the Data Protection Authority and Ethics committee was necessary.</li> <li>- in the case of research by public bodies, there had to be a substantial public interest</li> <li>- Genetic data was subject specific rules, authorisation of the Data protection Authority</li> </ul>	<ul style="list-style-type: none"> <li>- Appropriate measures to safeguard data (data minimisation and anonymisation)</li> <li>- Authorisation of data processing authority.</li> </ul>
<b>Conditions for further processing of health data</b>	Notification to Data Protection Authority Principle is consent of DS Consent not necessary if activity required by law or is included in a bio-medical or health care research program. Consent not necessary DS cannot be informed for legitimate grounds, OK of ethics committee;	
<b>What are the rights of the data subject?</b>	Data subjects had a right of access, update, rectification, to be informed of the sources, of the method of processing etc...	The GDPR provides the following rights: right to access by the data subject (Article 15); right to rectification (Article 16); right to erasure (Article 17); right to restriction of processing (Article 18); right to data portability (Article 20); as well as a right to object (Article 21).
<b>Possible derogation from the rights of the data subject</b>	Right to access, update, rectify, to be informed of the sources and method of processing etc... could be derogated from if it was impossible or required the use of disproportionate means.	Exemption of information is admitted if it proves impossible or involves disproportionate efforts or could make impossible or seriously affect the purposes of the research.