

COUNTRY: SPAIN

Theme/ question:	Under the Directive + National Law	Under the GDPR + National law
Legislation	Organic Law 15/1999 of 13 December on the Protection of Personal Data (the LOPD)	Amendment of LOPD, additional legislation expected with 2 years
Legal grounds applicable to scientific research purposes	Health data could be processed on the basis of consent or legal requirement, or for the purpose of preventive medicine, and diagnosis.	Health data may be processed on the basis of consent.
Safeguards required - Conditions framing the processing of health data for scientific research purposes	<ul style="list-style-type: none"> - The data should be processed by health professional and under confidentiality. - For genetic data, only explicit consent (stored for five years, more if anonymised) - For biomedical research, consent is required - Opinion of Ethics committee - Declaration to the Data Protection Authority - High level of protection of data (in particular to prevent unauthorised access), secrecy/ confidentiality 	GDPR requires the implementation of safeguards, An opinion from an Ethics committee must be obtained.
Conditions for further processing of health data	<p>Consent and prior information were necessary</p> <p>If the purpose of research were compatible no need to obtain consent again:</p> <ul style="list-style-type: none"> - When data are “depersonalised” (anonymised) - Initial consent may cover subsequent research (when related to initial research) applicable to identified or identifiable data) - Genetic data with authorisation of data protection authority, at least pseudonymised. 	
What are the rights of the data subject?	Data subjects had a right to be informed and to access the data concerning them being processed.	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).
Possible derogation from the rights of the data subject	Exemption of the obligation to collect consent was possible when transfer was imposed by law, or collected for public sources, or anonymised.	Derogations from the right of the data subject to access the data, the right to rectification and the limitation of their purposes are admitted if they would impair or render impossible the research project.