

COUNTRY: PORTUGAL

Theme/ question:	Under the Directive + National Law	Under the GDPR + National law
Legislation	<u>Law no. 67/98 of 26 October on Protection of Personal Data</u> <u>CNPD's Deliberation no. 1704/2015</u> – Applicable to the processing of personal data on the field of clinical research	Proposed bill to would amend the Law on protection of personal data.
Legal grounds applicable to scientific research purposes	Health data could be processed on the basis of consent or for scientific research purposes (Article 3 (a) DPA).	Health data may be processed on the basis of consent or for scientific research purposes (article 9 proposed new legislation)
Safeguards required - Conditions framing the processing of health data for scientific research purposes	<ul style="list-style-type: none"> - Notification to data protection authority, carried out by health professional, or someone with a similar duty of confidentiality. - Appropriate security measures. - Collection of sensitive data: prior checking of the Data Protection Authority specific authorisation. 	<ul style="list-style-type: none"> - GDPR safeguards, Anonymisation and pseudonymisation if possible. - Consent can be applicable to specific fields or several areas of research. - Positive opinion of competent Ethics committee.
Conditions for further processing of health data	Notification and authorisation of the Data Protection Authority. If impossible to obtain, consent requirement could be waived by the Data Protection Authority, this required a full explanation and demonstration (truly special situation), or the authority concludes there is an important public interest.	Same conditions
What are the rights of the data subject?	Data subjects had rights to object, rectify and to be informed, of the purpose and retention period.	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 derogations from the rights of the data subject	The obligation to inform could be waived, by decision of the Data Protection Authority, or the information is impossible or involves disproportionate efforts, or when the processing is required by law.	Derogations from the rights of access, rectification, limitation of processing and opposition are admitted under specific circumstances.