

COUNTRY: FRANCE

Theme/ question:	Under the Directive + National Law	Under the GDPR + National law
Legislation	Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés (1978 Data protection <u>Act</u>)	Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés (1978 Data protection <u>Act</u>) as amended to implement the GDPR
Legal grounds applicable to scientific research purposes	Data concerning health may have been processed on the basis of consent, but also for scientific research purposes (Chapter IX of the Act).	Data concerning health may processed on the basis of consent, but also for scientific research purposes (Chapter IX of the Act).
Safeguards required - Conditions framing the processing of health data for scientific research purposes	<ul style="list-style-type: none"> - Processing of anonymised data (if approval of anonymisation protocol) - Authorisation of the CNIL (or application of methodology of reference), ethical approval required 	<ul style="list-style-type: none"> - Processing of anonymised data, OR - Processing if identifying or pseudonymised data whilst implemented GDPR safeguards, and - Application of methodology of reference (or authorisation of the CNIL), ethical approval required.
Conditions for further processing of health data	The authorisation of the CNIL (or application of methodology of reference) and ethical approval was required for further processing.	The application of methodology of reference(or the authorisation of the CNIL), ethical approval is required.
What are the rights of the data subject?	Data subject had a right to be informed of the processing and to access the data concerning them.	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	Rights to object and to rectification (notification of transfer) may have been derogated to, under certain circumstances.	Articles 15, 16, 18 and 21 of the GDPR may be derogated to for scientific research purposes if they would render impossible or seriously impair the realisation of the processing purposes and were such derogation are necessary to achieve said purposes.