

COUNTRY: GERMANY

Theme/ question:	Under the Directive + National Law	Under the GDPR + National law
Legislation	Federal Data Protection Act - FDPA (Bundesdatenschutzgesetz – BDSG) Plus data protection legislation for each Land	The new FDPA – BDSG neu (2018) (<u>Act to Adapt Data Protection Law to Regulation (EU) 2016/679 and to Implement Directive (EU) 2016/680</u>) Plus data protection legislation for each Land
Legal grounds applicable to scientific research purposes	The processing of health data could be based on consent and scientific research purposes (private bodies is section 28 (6) and (8) FDPA and for Federation section 13 (2) No 8 and section 14 (2) No 9 FDPA).	The processing of health data can be based on consent and scientific research (new FDPA in section 27).
Safeguards required - Conditions framing the processing of health data for scientific research purposes	<ul style="list-style-type: none"> - Notification of processing - Authorisation of Data Protection Authority, - Possible consultation of ethics committee (recommended); - Data must be anonymised as soon as the research allows it, and may be stored in pseudonymised form, - In particular for genetic (pseudonymisation key kept by third party custodian) regular notification to data subjects. 	<ul style="list-style-type: none"> - Additional to the safeguards set in the GDPR, national legislation requires safeguards as well. Appropriate safeguards must be implemented by the Controller. - Data must be anonymised as soon as research is done. - Possible consultation of ethics committee (recommended).
Conditions for further processing of health data		Without consent (if necessary and interest of the controller substantially outweigh the interest of the DS) Appropriate safeguards must be implemented by the controller Data anonymised as soon as research is done. Possible consultation of ethics committee.
What are the rights of the data subject?	Data subjects had a right of access and the right to correction, erasure and blocking of the processing.	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	Private bodies : Exemption of obligation to information / notification if transfer or storage necessary for scientific research purpose, and notification would require a disproportionate effort. Public entities have no derogation.	Right to access, right of rectification, right of restriction and right to object may be suspended if they were to render impossible or seriously impair the research project.