

press release

Federal and state data protection authorities accept the consent documents of the Medical Informatics Initiative

04/30/2020

With the decision of April 15, 2020, the independent data protection supervisory authorities of the federal and state governments have accepted the updated consent documents of the medical informatics initiative of the Federal Ministry of Education and Research.

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The working groups for science and research as well as health and social affairs of the conference of the independent data protection supervisory authorities of the federal and state governments (DSK) accompanied the development of these sample texts and a handout for their application in an advisory capacity. In this process, it was a particular concern of the data protection conference that in every phase of a research project the processing of their data is transparently presented to the patients and that they have the appropriate opportunities to influence this. After an intensive coordination process, the DSK has now determined that there are no data protection concerns against the use of the current sample texts of the medical informatics initiative and the handout. The above The changes still required by the decision of the DSK have now been fully adopted in the consent documents and the handout (version 1.6d of the consent documents, consisting of patient information and declaration of consent as well as 0.9d of the handout).

The Medical Informatics Initiative is a project funded by the Federal Ministry of Education and Research, in which physicians, computer scientists and scientists from other disciplines at German university hospitals work together with the aim of improving research opportunities and patient care through the exchange and use of data from patient care and clinical and biomedical research across institutions and sites.

In order to ensure cross-site, controlled use and provision of patient data for medical research purposes, the Medical Informatics Initiative has drawn up sample texts for patient consent to the use of their personal data for medical research, including patient information.

The working groups Science and Research as well as Health and Social Affairs of the DSK will continue to support the project in an advisory capacity.

The letter from the DSK chair to the MII and the current sample texts are available here:

Downloads: Letter from the DSK chair of April 21, 2020.pdf (PDF / 826.61 KB) Handout as of April 16, 2020.pdf (PDF / 224.37 KB) Patient information and consent as of April 16, 2020.pdf (PDF / 292.59 KB)

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