Alliance of Science Organisations in Germany

Statement

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Responsible data protection regulations for efficient and productive research in Europe

Joint statement of the Alliance of Science Organisations on the General Data Protection Regulation of the European Union

A high and effective level of data protection in Europe is essential for research in order to create new knowledge and help meet social challenges, as people's willingness to provide personal data for innovative research projects is based on a binding assurance and realization of the confidential use of such data. Above and beyond statutory data-protection provisions, recognized and tested ethical standards and procedures already exist within the scientific community to protect the personal data of study participants, test persons and patients. On this basis and guided by the quest for knowledge, European science must be able to access new research fields with the help of socioeconomic and medical data and to achieve scientific breakthroughs.

At the European level, the negotiations of the EU institutions (known as the trilogue) regarding a General Data Protection Regulation, which will have significant implications for research, will begin at the end of June. The Alliance of Science Organisations is concerned that certain legislative proposals for this regulation could discourage or even prevent important research (for example in medical research and the social sciences). The Alliance of Science Organisations is therefore calling upon the members of the European Parliament, the representatives of the member states and the European Commission to take the following key points into consideration in the trilogue negotiations.

Consent to have data collected for research purposes
Scientific progress often depends upon uses of data for new research purposes that are not yet foreseeable in their entirety at the time the data is collected. This is true of many large-scale scientific investigations across Europe, for example cohort studies. The regulation should therefore make it possible to formulate consent for data collection in such a way that the individuals concerned can consent to more wide-ranging data processing for research purposes or research areas. Extensive positive experience has already been gained with this type of consent declaration in the field of biobanks.

Pseudonymization of data
Depending on the aims, anonymized and pseudonymized data are extremely important for research. According to current legislation, pseudonymization is an instrument that simplifies research with non-anonymous data and at the same time ensures the greatest possible level of protection of the personal rights of those concerned. Researchers have had good experience with the use of pseudonymized data, for example in the social sciences (scientific use files) and in biomedical research (e.g. in clinical trials). The regulation should contain an adequate definition of anonymous and pseudonymous data, taking into account the principle of proportionality. In this context, the expansion of the definition of personal reference is controversial. It would be sensible to retain the current definition of relative personal reference in the regulation.

Further processing of data already collected for research purposes
With regard to new research projects, science relies on the ability to reprocess existing data in the light of altered queries. By linking data sets already collected, hitherto unknown relationships and interactions can be identified, for example between different disease entities. Based on this perspective, modern infrastructures for research data have been established in Europe for many years. The regulation should therefore allow data already collected to be further processed under facilitated conditions for research purposes.

Research with medical and genetic data
Medical data and genetic data are particularly sensitive and therefore worthy of protection. Science takes this into account by applying stringent ethical protective mechanisms (e.g. the Heidelberg practice of whole genome sequencing). Nevertheless, research with such data is essential for high-quality, innovative public healthcare and should not be compromised. The regulation should therefore facilitate reprocessing of medical and genetic data on the basis of existing protective mechanisms without the need to obtain separate consent for every instance of processing. Obtaining such consent would be impracticable, especially in the case of research with large data sets on many individuals. Moreover, obtaining separate consents would also be methodologically dubious, as it would result in an uncontrolled preselection of the underlying data sets.

Provision of information to those concerned
Providing information on the content and aim of the scientific processing of data forms an important foundation for the trust of individuals who provide their personal data for research purposes. A corresponding right to information is enshrined in existing law, and this also applies to research data. However, in practice (e.g. in the case of extensive data sets on many individuals), this can place a disproportionate burden on science. The regulation should therefore provide appropriate facilitations for researchers with regard to information obligations so as not to disproportionately hinder the use of data already collected.

General opening clause for research
Cross-border research projects in particular benefit from uniform data protection regulations throughout Europe. Nevertheless, some of the member states have established specific procedures for dealing with data protection issues in research practice (e.g. ethics committees, data protection officers and data protection authorities). The regulation should therefore contain a general opening clause for research in order to implement research-specific modifications to the laws of the member states that are not contained in the general data protection standard of the regulation.

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