The new EU General Data Protection Regulation 2016/679 and Clinical Research

Prof. Dr. Joerg Hasford

President, Association of Medical Research Ethics Committees in Germany
Email: has-ethik@ibe.med.uni-muenchen.de
Web: www.akek.de

The EU GDPR

- **Published in the Official Journal of the EU May 4th, 2016**
- **Entered into force May 25th, 2018**
- **88 pages, 173 recitals, 99 articles**
- **Is directly applicable in all EU MS**

Presentation focusses on relevant issues in clinical trials and medical research.

AMEK Hasford

The EU GDPR - Objectives

1. This Regulation lays down rules relating to the **protection of natural persons** with regard to the processing of personal data and rules relating to the **free movement of personal data**.
2. This Regulation protects fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data.
3. The free movement of personal data within the Union shall be neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data.

Art.1 EU GDPR

The EU GDPR – Objectives

The processing of personal data should be designed to serve mankind. The right to the protection of personal data is not an absolute right; it must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality. This Regulation respects all fundamental rights and observes the freedoms and principles recognised in the Charter as enshrined in the Treaties, in particular the respect for private and family life, home and communications, the protection of personal data, freedom of thought, conscience and religion, freedom of expression and information, freedom to conduct a business, the right to an effective remedy and to a fair trial, and cultural, religious and linguistic diversity. (Recital 4)

The EU GDPR - Lawfulness of processing

Processing shall be lawful only if and to the extent that at least one of the following applies:

(a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

Art.6 , EU GDPR

The EU GDPR - Conditions for Consent

1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data. → written Informed Consent

Art.7, EU GDPR

AMEK Hasford

The EU GDPR - Conditions for Consent

2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.

Art.7, EU GDPR

AMEK Hasford

The EU GDPR - Conditions for consent

3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent ***before*** its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.

It remains unclear whether such data can be used/analysed after withdrawal of consent.

Art.7, EU GDPR

The EU GDPR - Conditions for consent

4. When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.

Art.7, EU GDPR

AMEK Hasford

Information to be provided where personal data are collected from the data subject

- the identity and the contact details of the controller and, where applicable, of the controller's representative
- the contact details of the data protection officer, where applicable
- the purposes of the processing for which the personal data are intended as well as the legal basis for the processing;
- the recipients or categories of recipients of the personal data, if any
- where applicable, the fact that the controller intends to transfer personal data to a third country or international organisation

Art.13, EU GDPR

AMEK Hasford

Information to be provided where personal data are collected from the data subject

- the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;
- the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;
- where the processing is based on point (a) of Article 6(1) or point (a) of Article 9(2), the existence of the right to withdraw consent at any time, without affecting the lawfulness of processing based on consent before its withdrawal;
- the right to lodge a complaint with a supervisory authority;

Art.13, EU GDPR

AMEK Hasford

Information to be provided where personal data are collected from the data subject

- **the existence of automated decision-making, including profiling, referred to in Article 22(1) and (4) and, at least in those cases, meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject.**

Art.13, EU GDPR

All due at the time when personal data are obtained.

Art. 15 'Right of access by the data subject' specifies the rights to obtain from the controller all the information detailed in Art.13 and a copy of all personal data processed.

AMEK Hasford

The EU GDPR – Broad Consent

It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. **Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research.** Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.

Recital 33, EU GDPR

Transfers of personal data to third countries or international organisations (Art. 44-50)

Options

- Adequacy Decision by the European Commission
- Binding Corporate Rules
- Standard Data Protection Clauses adopted by the European Commission (template provided)
- Informed Consent, having been informed about all potential risks.

For clinical trials' data SDPC are used most often by pharma.

Joint Controllers (Art. 26)

Where two or more controllers jointly determine the purposes and means of processing, they shall be joint controllers. They shall in a transparent manner determine their respective responsibilities for compliance with the obligations under this Regulation.. The essence of the (written) arrangement shall be made available to the data subject.

In clinical trials Joint Controllers are considered to be the rule.

The EU GDPR – Data breaches

Art. 33 Notification of a personal data breach to the supervisory authority

- within 72 hours -

Art. 34 Communication of a personal data breach to the data subject

The EU GDPR – Ongoing trials

Directive 95/46/EC should be repealed by this Regulation. Processing already under way on the date of application of this Regulation should be brought into conformity with this Regulation within the period of two years after which this Regulation enters into force. Where processing is based on consent pursuant to Directive 95/46/EC, **it is not necessary** for the data subject to give his or her consent again if the manner in which the consent has been given is in line with the conditions of this Regulation, so as to allow the controller to continue such processing after the date of application of this Regulation.

Recital 173, EU GDPR

Consistent Application of the GDPR in the EU

European Data Protection Board

The Board shall be composed of the head of one supervisory authority of each Member State and of the European Data Protection Supervisor.

Tasks: the Board shall ensure the consistent application of this Regulation.

(Art.60)

Conclusions

- The EU GDPR strenghtens the protection of natural persons.
- Data protection issues need more attention, get more complicated, and costly.
- Broad Consent is permitted.
- The EU Member States have the right to implement the EU GDPR in many respects in agreement with their own policies and traditions. Thus national laws and regulations have to be complied with also in the future.