LEGAL PROCESSING OF PERSONAL DATA

IN CLINICAL TRIAL

On 23 January 2019, EDPB [1] adopted Opinion [2] on the relationship of the Clinical Regulation testing [3] and the General Data Protection Regulation [4] .

Although the application of the Clinical Trials Regulation has been postponed and is expected the beginning of application only in 2020, [5] in the Slovak legal system is a clinical trial regulated by several laws [6] , the Office identifies with the legal bases of personal processing data for the purposes of the clinical trial, which, according to the opinion, are to be applied regardless of whether the Clinical Trials Regulation applies.

Processing of personal data for the purposes of the clinical trial protocol [7]

According to the opinion, this is the primary use of clinical trial data. In this case, distinguishes between two types of processing activities that have different legalities basics:

1. **Processing operations to ensure reliability and safety** [8]

The appropriate legal basis for the processing of personal data for this purpose is Art. 6 par. 1 letter c) General Data Protection Regulation - **processing necessary to comply with the law obligations of the operator** .

As regards the fulfillment of the condition for the lawful processing of a specific category of personal data, the condition in Art. 9 par. 2 letter (i) the General Regulation on the protection of personal data data **processing - is necessary for reasons of public interest in the public domain health, such as protection against serious cross - border threats to health or ensuring a high level of quality and safety of healthcare and medicines; or medical devices, under Union law or the law of a Member State lay down appropriate and specific measures to protect the rights and freedoms of the person concerned, in particular professional secrecy.**

[1] European Data Protection Board, more information at https://edpb.europa.eu/edpb_en
[2] Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the GDPR, currently available in English only at https://edpb.europa.eu/our-work-tools / our-documents / opinion-art-70 / opinion-32019-concerning-questions-and-answers-interplay_en
[3] Regulation (EU) No 182/2011 of the European Parliament and of the Council 536/2014 of 16 April 2014 on clinical trials of medicinal products on human use repealing Directive 2001/20 / EC
[4] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to processing of personal data and on the free movement of such data, repealing Directive 95/46 / EC (General Data Protection Regulation)
[5] Point 3 of the opinion
[6] Eg. Act no. 362/2011 Coll. on Medicines and Medical Devices and on Amendments to Certain Acts
[7] More detailed information is provided in section 2 of the opinion
[8] For more details, see section 2.1 of the opinion

2. **Processing operations relating to purely research activities** [9]

Possible legal bases for processing:

a) Art. 6 par. 1 letter a) general regulation on personal data protection - **consent** , in conjunction with Art. 9 par. 2 letter (a) of the General Data Protection Regulation for the processing of a special category of personal data - **explicit consent** .

Informed consent under the Clinical Trials Regulation is not to be confused with (explicit) consent under the General Data Protection Regulation. There are two types of consents. The legal basis for consent within the meaning of the General Data Protection Regulation, which is decisive for the processing of personal data does not, in the opinion, appear to be the most appropriate, as it is disputed whether the sponsor or the investigator and the participant in the clinical trial are not in the same position, and it may therefore appear that the consent was not given freely.

b) Art. 6 par. 1 letter (e) or (f) of the General Data Protection Regulation - **fulfillment of a task carried out in the public interest** or **legitimate interests operator** .

These legal bases appear to be more appropriate compared to the above option. However, processing is only possible if one of the conditions is met for the processing of a specific category of personal data

i. Art. 9 par. 2 letter (i) of the General Data Protection Regulation - **processing is necessary for reasons of public interest in the public domain health, under Union or Member State law,** or
ii. Art. 9 par. 2 letter (j) of the General Data Protection Regulation - **processing is necessary for the purposes of scientific research pursuant to Article 89 (2). 1 on the basis of Union law or the law of a Member State.**

Processing for purposes not specified in the clinical trial protocol, for scientific purposes only purposes [10]

The Regulation on Clinical Trials in Art. 28 par. 2 requires the consent of the person concerned for these purposes. We emphasize again that informed consent under the Clinical Trials Regulation is not the same as (explicit) consent under the General Data Protection Regulation.

[9] For more details, see section 2. 2 of the opinion
[10] More detailed information is provided in section 3 of the opinion