GUIDELINES 07/2020 ON THE CONCEPTS OF CONTROLLER AND PROCESSOR IN THE GDPR

European Data Protection Board
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Comments on draft EDPB guidelines – on the concepts of Controller and Processor in the GDPR

The TIC Salut Social Foundation, as Catalan Health System DPO, would like to submit the following comments on EDPB's draft Guidelines 07/2020 on the concepts of controller and processor in the GDPR (version for public consultation)

General remarks

We welcome all guidelines from EDPB.

When it comes to the draft regarding the concepts of Controller and Processor in the GDPR, we think its value and usability would improve if the final version had more references and examples for the interpretations that the recommendations are based upon.

Specific concerns

1) The draft's concepts of Controller and Processor seem to lack to determine the role of the external DPO.

   The draft does not include any reference when it comes to the definition of the role of an external Data Protection Officer (DPO). This is a reading of major relevance to clarify what happens to the legal position of the external DPO when he receives personal data on behalf of the controller or processor in the performance of his duties. It is clear that the mere act of receiving and holding this data qualifies as processing it for the purposes of the GDPR (art. 4(2) GDPR), and there are no exceptions or special regimes for the DPO role.

   In our view, a processor may only process data according to the instructions given by the controller (art. 28(3)(a) GDPR). The DPO, however, cannot receive instructions regarding the exercise of his tasks (art. 38(3) GDPR).

   Given this understanding, more emphasis should be given in the references to the external DPO and its role as a data controller by default.

2) More guidance on the interplay with the clinical trials regulation (par. 66)

The example on the Clinical Trial provides a clear illustration, but references to the different roles should be clarified to improve the interplay with the clinical trials regulation.

In this regard, the last paragraph of the Clinical Trials example on page 18 refers that in the event that the health care provider (the investigator) does not participate to the drafting of the protocol (he just accepts the protocol already elaborated by the university (the sponsor)), and the protocol is only designed by the sponsor, the investigator should be considered as a processor and the sponsor as the controller for the respective clinical trial.

In our view, this interpretation may be misleading with the day-to-day practice. The health care provider and the sponsor jointly decide aspects related to the carry out of the trial (i.e. cohort of patients, objectives and scope of the study, personal information that may need to be treated, etc.). Thus, it would seem reasonable to establish in all cases a joint responsibility or co-responsibility for the processing of personal data (identified or pseudonymised) necessary to carry out the clinical trial, as foreseen in article 4.7 of the GDPR.

Hence, we suggest that the example related to the Clinical Trial on page 18 to be adjusted due to in practice the large pharmaceutical companies send the protocols drafted to the investigator, and, except otherwise adjusted, we would always be in the default interplay of the investigator as processor and the sponsor as the controller for the respective clinical trial.

This understanding that the investigator and the sponsor will be jointly responsible in a clinical trial is more in line with reality, considering that the investigator and the sponsor are the ones who define what personal data processing will be carried out for the trial, determining aspects such as: the cohort of patients, objectives and scope of the study, personal information that may need to be processed, among others.

Indeed, linked to clinical trials, the draft should also refer to the functions of the Clinical Trial Monitors and their role vis-à-vis both the sponsor and the investigator.

This relation requires in our view specific reference to clarify that according to his functions, the Monitor should be considered as data processor of both the sponsor and of the investigator and, thus, to be governed by a contract or other legal act under EU or Member State law between the controller and the processor, as required by Article 28(3) GDPR, with each of them

3) More guidance regarding the joint controllership in the public sector (par. 169-173)

We suggest that the draft should also include more guidance on the form of the arrangement between joint controllers based on legal acts when it comes to the public sector.

It should reflect that a parent institution may establish by means of legal acts joint controllership over its affiliated and should be also be accompanied by examples, linked to the possible structure within the public authorities under Member State law to which the controllers are subject.

Best regards,
for TIC Salut Social Foundation – Catalan Health System DPO

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