

## **European Data Protection Board Guidelines on Processing Health Data for Scientific Research in the Context of the Covid-19 Outbreak**

On 21 April 2020, the European Data Protection Board (**EDPB**) adopted guidelines for the processing of personal data concerning health for the purposes of scientific research in the fight against Covid-19 (the **Guidelines**). One of a myriad of guidance documents published by the EDPB in relation to the ongoing Covid-19 crisis, these Guidelines, which apply to both public as well as private organisations involved in research, provide guidance on how to reconcile scientific research with data protection requirements. In particular, the Guidelines discuss the legal basis for such activity, the implementation of adequate safeguards, and the exercise of data subjects' rights. While these Guidelines address the most urgent questions, the EDPB will publish more detailed guidance on this area later this year.

As it has done in other documents dealing with the fight against Covid-19, the EDPB underlines that data protection rules do not prevent measures being taken in the fight against Covid-19. The GDPR explicitly addresses situations such as these and provides special rules for the processing of health data in a manner which respects the fundamental rights to privacy and personal data protection.

### ***Legal basis***

The EDPB notes that consent provides a legal basis for the processing of personal data (Article 6 (1) (a) GDPR). Explicit consent could provide a legitimate basis for scientific research. However, the controller must make sure that consent is obtained in compliance with the strict requirements of free, specific, informed and unambiguous consent. Moreover, data subjects must have the possibility of withdrawing their consent.

In addition, Member States may enact specific laws pursuant to Article 6 (1) (e) or 6 (1) (f) GDPR in combination with the enacted derogations under Article 9 (2) (j) or Article 9 (2) (i) GDPR for the processing of personal (health) data for scientific research. Where such a law has been enacted and applies to the controller, these provisions can provide a legal basis for the processing.

The Guidelines also indicate that it is important to distinguish between primary and secondary use of data for research purposes. Unfortunately, the EDPB does not address the consequences of this distinction at this point, as it refers to later guidelines that will address this matter.

### ***Data protection principles***

Considering the great amount of personal data that may be processed, the EDPB emphasizes the importance of processing the personal data in accordance with the principles of Article 5 GDPR. In particular, the processing must respect the principles of transparency, purpose limitation, data minimization and storage limitation and the principle of integrity and confidentiality.

As regards the principle of integrity and confidentiality, the Guidelines indicate that these measures should *at least* consist of “*pseudonymization, encryption, non-disclosure agreements and strict access role distribution, restrictions as well as logs*”. Furthermore, a data protection impact assessment under Article 35 GDPR is likely to be required and the measures that are implemented should be documented in the record of processing activities.

***Data subjects' rights***

In addition, data subjects must be informed about the processing and about the purposes of processing. The EDPB adds that situations such as the current Covid-19 outbreak do not suspend or restrict the possibility of data subjects exercising their rights pursuant to Articles 12 to 22 GDPR. However, Article 89 (2) GDPR allows the national legislator to restrict (some) of the data subject's rights as set out in Chapter 3 of the GDPR. Therefore, the restrictions may vary depending on the laws enacted in the particular Member State.

***International transfers***

Finally, the EDPB notes that there could be a need for international cooperation that might also involve international transfers of health data for the purpose of scientific research outside of the EEA. In the absence of an adequacy decision pursuant to Article 45 (3) GDPR or appropriate safeguards pursuant to Article 46 GDPR, public authorities and private entities may rely upon the applicable derogations pursuant to Article 49 GDPR. In this regard, the EDPB considers that the fight against Covid-19 has been recognized by the EU and most of its Member States as an important public interest, which could open the door for allowing international transfers that are "*necessary for important reasons of public interest*" on the basis of Article 49 (1) (d) GDPR.

The Guidelines are limited in scope, but contain some useful examples that will be helpful to ensure that urgent research projects set up in the context of the current crisis are in line with the GDPR. The EDPB Guidelines can be found [here](#).