

ARBEITSKREIS MEDIZINISCHER ETHIK-KOMMISSIONEN

IN DER BUNDESREPUBLIK DEUTSCHLAND e. V.

- DER VORSTAND -

AK Med. Ethik-Kommissionen ◦ Charlottenstraße 42 ◦ 10117 Berlin

Public Consultation regarding COMMISSION IMPLEMENTING DECISION (EU) .../... of XXX on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council

The Association of Medical Ethics Committees in Germany represents all Medical Ethics Committees in Germany that are involved in the assessment of clinical trials with medicinal products, medical devices or radiation exposure. We appreciate that the European Commission has initiated a public consultation on the draft standard contractual clauses (SCC) for the transfer of personal data to third countries. This offers the chance to contribute to the further improvement of this document. However the time frame for commenting is much too short to allow a thorough review. Thus we focus our comments on some obviously important issues without being able to annotating details due to lack of time.

General Comments

Progress in medicine is urgently needed, thus research is absolutely essential and should not be impaired unless human rights are at risk. Medical Ethics Committees have thus two major responsibilities: to protect research participants rights and well-being, and to protect the freedom of research. There is no doubt that the exchange and transfer of data and biosamples is an indispensable part of medical research and translational medicine. Given that the research participants typically risk their health when they volunteer for clinical trials (as the benefits and risks are not yet known) primarily for the benefit of future patients and of public health at large, they deserve that their data are effectively protected from any unauthorized use. We are aware that there is no 100%-data safety, but we are convinced that the current draft needs some enforcement. This enforcement is even more important as once the public trust in the confidentiality of personal health-related data in clinical research has been deceived, the willingness to participate in clinical research will be seriously reduced. This would be the worst case for the future of clinical research in the EU.

1. The current draft of the SCC does not properly address and solve the problems of an unauthorized access to personal data by others, e.g. intelligence services or competitors. We miss any realistic solution

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regarding the activities performed under the US CLOUD Act, the FISA and the Patriotic ACT, and those of the so called Five Eyes („FVEY“, an intelligence alliance comprising Australia, Canada, New Zealand, the United Kingdom and the United States. These five countries are parties to the multilateral UKUSA Agreement, a treaty for joint cooperation in signals intelligence). But China has to be mentioned in this context too. According to the current state of legal practice in these countries, especially their intelligence cooperation and the associated powers of intervention and investigational practices, the SCC cannot be used at all when transferring personal data to one or more of these countries as their privacy is definitely not secured. More specifically: with regard to the current situation in the US, but also in other states, e.g. in China, it seems unrealistic that contractors are able to guarantee that they will not be prevented from fulfilling their obligations by their own domestic law as it is required by Clause 2a and Consideration 19. Therefore it is difficult to see how these clauses could be of any help to make data transfer to such states admissible. It is of the utmost urgency to clarify how the conditions set up by the SCC can be fulfilled by data exporters and importers.

2. Not only should the „encryption during the data transfer“ be listed, but also end-to-end encryption ("E2EE") on the client side and encrypted storage at the importer without interrupting the encryption chain (i.e. in particular no re-encryption). This should be specified as an indispensable standard. Simple transport encryption alone shall not be deemed to be enough.
3. With regard to the transferring of biomaterial as part of scientific research, further clarifications for controllers and competent authorities should be made. Particularly in the light of footnote 2 of Annex to the COMMISSION IMPLEMENTING DECISION it should be taken into account that according to Art. 4 (13) and (5) GDPR, biomaterial always relates to a single person. By that definition such biomaterial as genetic data carrier could possibly neither be pseudonymised nor anonymised in a non-destructive manner, so the intended use for scientific research would be limited or impossible.
4. Many software used in clinical research allow the manufacturer to access the data that is processed with the particular software. This problem should be addressed too.

We hope in the interest of the patients and healthy volunteers participating in clinical research and in the interest of innovative research in the EU that the European Commission will meet our concerns adequately in the final version of the SCC. As a 100%-data safety will not be achievable the European Commission should consider to establish an insurance that compensates research subjects for the consequences due to data safety breaches.

9.12.2020

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