

## 13 Storage limitation

*Clinical research projects funded by the DZHK take place in the public interest and the measures required by Art. 89 GDPR to protect data (separation of powers, data minimisation, pseudonymisation, anonymisation) are implemented. Storage for an indefinite period is essential for the collection of data and biomaterials to be used beyond the study period.*

*Are the storage and use of personal data and research data still permissible for an indefinite period of time after the data subject has been informed about this and has consented accordingly?*

As a rule the GDPR does not allow infinitely long storage of data on stock. In article 5 GDPR, that formulates the essential principles of the data processing, it is said under lit. e) that personal data shall be

*“kept in a form which permits identification of data subjects for **no longer than is necessary** for the purposes for which the personal data are processed; personal data may be stored **for longer periods** insofar as the personal data will be processed solely for archiving purposes in the public interest, **scientific** or historical **research** purposes or statistical purposes in accordance with Article 89 (1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject (‘storage limitation’)”*  
[Highlighting not in the original text]



The right to erasure and right to be forgotten correlating with the principle of the storage limitation is laid down in Article 17 GDPR. As already explained above under Part II.3.2, personal data are to be erased according to the provisions of the Article 17 para. 1 GDPR if not one of the exceptions according to Article 17 para. 3 GDPR comes into play. Thus Article 17 para. 3 lit. d) GDPR states that the right to erasure and the right to be forgotten according to Article 17 para. 1 and 2 GDPR are not to be applied if the processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89 para. 1 GDPR in so far as the right referred to in Article 17 para. 1 GDPR is likely to render impossible or seriously impair the achievement of the objectives of that processing. This would still mean, that in these cases, however, the data must be deleted immediately after the goal has been achieved.<sup>44</sup>

As the GDPR only allows storage for **longer periods**, but does not provide a maximum storage period, there is controversy as to whether the examination, whether the further storage is necessary for these purposes, can be waived<sup>45</sup> or not.<sup>46</sup>

According to the view expressed here, a potentially infinite storage can theoretically result as an exception to the principle of storage limitation, especially in the case of a broad consent. In order to avoid uncontrolled data retention, however, regular checks should also be carried out in the case of a broad consent to determine whether the purpose has been achieved. If, for example, one assumes that a disease to be investigated after broad consent is considered cured or that a research institution decides that no more research is to be carried out in a certain area (e.g. clinical trials of medicinal products), then a purpose may have been achieved or erasure may be necessary because a purpose has been abandoned.

*How is the retention period of consent and research data defined by the GDPR?*

GDPR does not define retention periods of consent and research data. However, retention obligations may result from technical legislation of the European Union or the Member States depending on the type of research project.

*Is it advisable to secure the storage period of the data and the consents by the consent itself?*

Yes, since consent must be informed in order to be effective, it must cover all essential aspects. This would also include a potentially infinitely long storage period in the case of a broad consent. It is not necessary to indicate that the consent form itself will be kept for as long as the research continues.

44 Koch/Schütze/Spyra/Wefer, in: Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie e.V. (GMDS), Gesellschaft für Datenschutz und Datensicherheit e.V. (GDD), Data protection requirements for medical research, taking into account the EU General Data Protection Regulation (GDPR), 16 May 2017, p. 35.

45 Kühling/Buchner/Herbst, 2. Aufl. 2018, DS-GVO Art. 5 Rn. 69.

46 Simitis/Hornung/Spiecker gen. Döhmman, Datenschutzrecht, DSGVO Art. 5 Rn. 162.