14 Purpose limitation

At present, the study consent also allows the use and transfer of personal data for biomedical research projects. The consent is obtained without the possibility to exclude this purpose. According to Art. 5b) GDPR "further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89 (1), not be considered to be incompatible with the initial purposes".

Can further processing for purposes other than the study purpose (but nevertheless within the framework of research) be carried out in accordance with consent?

The GDPR permits a broad consent, which does not have to be limited to a specific research project anymore. A processing of personal data for several research projects, which are covered by this broader understanding of purpose limitation, can therefore take place on basis of the same declaration of consent, provided that it was formulated in conformity with the law and was obtained effectively. For this purpose it is particularly important that the essential information for a declaration of consent is still correct; for example, the data may not be processed by a new data controller.

It may however be a difficult question in individual cases whether a broad consent still meets the requirements of the principle of purpose limitation. The central prerequisite for effective consent is its specificity. A blanket con-

sent clause, which is not limited to specific data processing purposes, will as a rule be ineffective. On the other hand, consent does not have to be limited to a single data processing purpose. Article 6 para. 1 lit. a) and Article 9 para. 2 lit. a) GDPR explicitly state, that the data subject can give consent "for one or more specific purposes". Admittedly, the purpose must in principle be as precise as possible at the time of data collection and it must be ensured that personal data are not processed for purposes which the data subject did not have to expect at the time of collection.[47] But at the same time recital 33 GDPR states, that it should be possible for data subjects to give their consent for **certain areas of scientific research** and not only for specific research projects anymore. This is intended to address the problem of science that the purposes of data processing in the field of scientific research often cannot be fully stated at the time of data collection.

This, however, raises the question of what is meant by "certain areas of scientific research". In the explanatory memorandum on the reform of the Tenth Book of the German Social Code (SGB X) the German legislator made it clear that it also adheres to the main features of the specific consent pursuant to Art. 4 No. 11 DS-GVO within the Broad Consent framework and does not, for example, permit the obtaining of a universal consent.[48] For example, a reference to research purposes in general ("open consent") does not satisfy the principle of specificity even in the context of Broad Consent.[49] At least the research area must be explicitly defined beforehand. Accordingly, the legislator demands that the research area must not be too general and must refer to a thematically defined field which is gradually concretised.[50] However, it is not clear from the explanatory memorandum how narrow the thematically defined research area must be in detail and whether the person concerned must be informed about the concretisation. However, Article 13 para. 1 lit. c) and Art. 14 para. 1 lit. c) GDPR stipulate that the data subject must be informed of the "purposes of data processing". The information must be specific enough to enable the data subject to form a clear picture of which data are processed and for what purpose. There are good reasons why the broad formulation "biomedical research projects" still falls within the scope of broad consent. This represents the current status of interpretation of "broad consent" by the Medizininformatik-Initiative and has some likelihood to be accepted in the still ongoing process of alignment with the data protection authorities.[51]

The question whether Article 5 para. 1 lit. b) second half-sentence GDPR is to be applied, arises only in the context of an examination of the compatibility

47 Kühling/Buchner/Buchner/Petri, 2. Aufl. 2018, DS-GVO Art. 6 Rn. 178–180.
48 BT-Drs. 18/12611, S. 113.
49 *Heberlein*, in: Ehmann/Selmayr, DS-GVO, 2017, Art. 6 Rn. 9.
50 BT-Drs. 18/12611, S. 113.
51 https://www.medizininformatik-initiative.de/sites/default/files/2019-05/MII_AG-Consent_Einheitlicher-Mustertext_v1.6a.pdf

of the purposes according to article 6 Abs. 4 GDPR. This would be the case, if the new research project would fall outside the scope broad consent and therefore outside the scope of "biomedical research projects". Since the processing of personal data in this case would be based on consent, the interpretation must first and foremost correspond to the wording of the consent. A limitation resulting from the wording cannot be circumvented by the general interpretation rule of Article 5 para. 1 lit. b) second half-sentence GDPR. This rule of interpretation does not mean, moreover, that purposes of scientific research are always compatible with the original purpose, but are not per se incompatible with the original purpose, taking into account Article 89 GDPR.