10 Authorisation of Study Leaders

To date, the central study leaders have had the right to access and at least view all medical, laboratory and image data of a study participant in other centres.

Do these persons also have the right to view all identifying data of the study participants?

What about multicentre studies? Do the German Medicines Act (Arzneimittelgesetz—AMG) and the Medical Devices Act (Medizinproduktegesetz—MPG) studies contain any requirements in this respect?

The term "*study leader*" is not a term used in the German Medical Law. For the purpose of further evaluation, it is assumed that by "study leader" the "*principal investigator*" is meant, as defined in Article 2 lit. f) Directive 2001/20/EC[37] which reads as follows:

"'investigator': a doctor or a person following a profession agreed in the Member State for investigations because of the scientific background and the experience in patient care it requires. The investigator is responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader responsible for the team and may be called the ***principal investigator****" [highlighting not in original text]*

37 In that sense also: Pommerening/Drepper/Helbing/Ganslandt, Leitfaden zum Datenschutz in medizinischen Forschungsprojekten—Generische Lösungen der TMF 2.0, 2014, p. 229.

This definition corresponds to the content of Section 4 para. 25 AMG, where, however, no separate term is coined for the head of the group. A Definition equivalent to Article 2 lit. f) Directive 2001/20/EC can be found in Section 3 No. 24 MPG.

None of these laws stipulate that a principal investigator may not have access to IDAT or must have such access. Therefore, the general principle is that those individuals who need access to IDAT to perform their duties in a research project should have access to that data. Conversely, persons who do not require IDAT must be excluded. If this is to be defined using generic role concepts, it is recommended to restrict access by default and to grant further authorisations if this is necessary in respect to the specific research project in view of the circumstances of the individual case. For example, if a principle investigator in a multi-center setting has mainly a coordinating function with regard to the different study sites, it would most likely not be necessary that the principal investigator has access to IDAT.

It should be noted that apart from the AMG or the MPG the federal state hospital laws applicable to the hospitals in which the study is being conducted may contain more specific rules—this may have to be checked individually for each hospital depending on the type of the study.

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Of course, a corresponding declaration of consent of the patient enables the processing of IDAT. The patient shall be informed that the principal investigator belongs to the circle of persons who can process IDAT collected during the multicentre trial.