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Summary

Survey of ethics committees on the application of Art. 34 HRA

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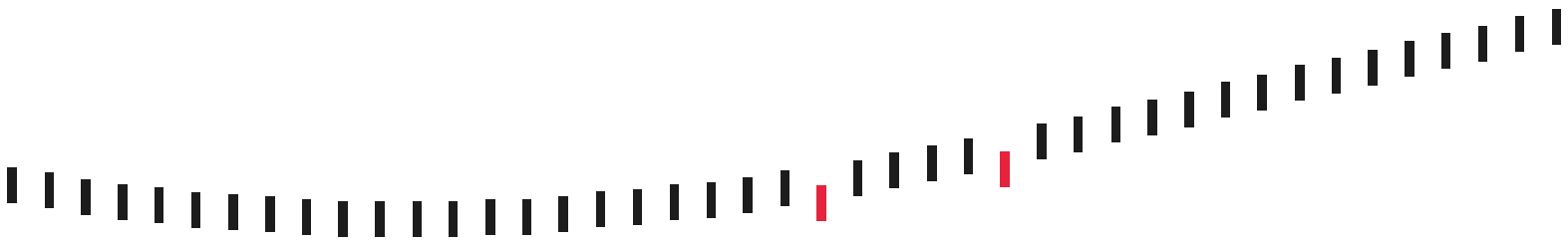

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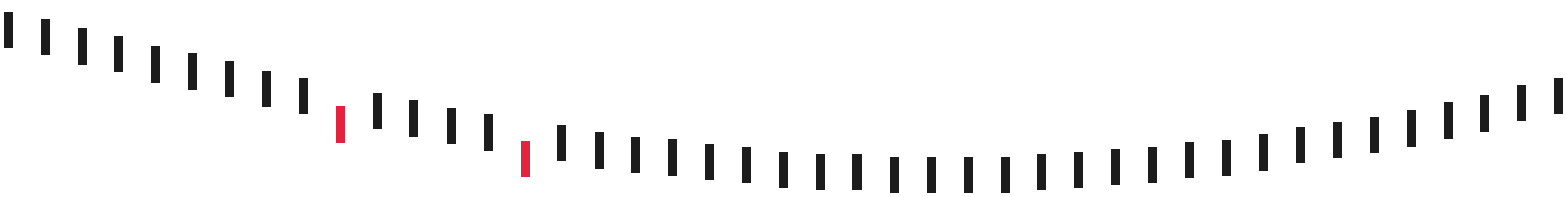
The key facts in brief

The Federal Act on Research involving Human Beings (Human Research Act – HRA) allows further-use projects to be carried out, subject to certain conditions, even in the absence of the informed consent of the persons concerned (Art. 34 HRA). The Federal Office of Public Health (FOPH) has commissioned the consultants BSS Volkswirtschaftliche Beratung to conduct a survey of ethics committees to find out how they deal with applications submitted under Art. 34 HRA. The findings in brief:

- *Applications:* Although consent for using part of the data/samples often exists in applications submitted under Art. 34 HRA, this does not apply to all datasets. As of last year (2020), such mixed applications have been recorded separately, whereas they were previously counted as applications "without consent". One initial analysis by an ethics committee shows that around a quarter of all applications for further use are mixed applications. Moreover, the applications submitted under Art. 34 HRA increasingly involve relatively old data/samples and the data volume is comparatively high.
- *Assessment:* The trend towards a high data volume may be connected with the criteria that need to be fulfilled in order for Art. 34 HRA to apply. For example, requirement a) "impossibility, disproportionality, undue burden" is one criterion for the application of Art. 34 HRA. Disproportionality is assessed partly via the number of datasets. While there are no clear limits, guide values are used. These vary considerably (50-500 persons, from whom it would be disproportionately difficult to obtain consent). But there are no formalised criteria or fixed requirements. The ethics committees believe that this is unlikely to be useful or feasible. In the first place, the specific situation is decisive, and secondly, the criteria sometimes have to be assessed in relation to each other. The occasionally differing practices of the ethics committees in their assessment (e.g. as regards the efforts that have to be made by the researchers to contact people) are considered by some to be bothersome (for example in multicentre studies).
- *Decision:* While the ethics committees require consent to the use of *all* data/samples to be obtained in only a relatively small percentage of cases (approx. 5-10%), consent often has to be obtained for *part* of the data/samples. This situation was described as relatively common to very common, and one ethics committee quantified it at 30%. When consent has to be obtained, the imposition of restrictions and/or conditions will depend on the particular ethics committee. In practice, however, the difference between restrictions and conditions associated with Art. 34 HRA applications is fairly minimal.
- *Procedures:* Most ethics committees routinely employ the simplified procedure when assessing the Art. 34 HRA applications, while the ordinary procedure is only rarely used (exception: one ethics committee follows the ordinary procedure as a matter of course). The ordinary procedure tends to be used when the three members on the simplified procedure committee are unable to agree. In three ethics committees, the applications submitted under Art. 34 HRA are sometimes discussed in the context of the ordinary procedure. Example: In one ethics committee, the applications are usually discussed in an ordinary session, and all committee members present are involved in the decision. The actual decision is issued in the simplified procedure, however. The composition of the three-member simplified procedure committee is subject to change in five ethics committees, whereas two ethics committees have set up a specific group comprised of doctors and other specialists for this purpose.



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