

Biobanking Project

DZHK “basic” biobanking

Provided the subject consents, all DZHK studies are required to collect a distinctly specified so-called DZHK biobanking¹ set from each study participant at timepoint 0 (i.e. at baseline prior to any intervention). Details on the DZHK biological materials will be documented in the DZHK laboratory information and management system (LIMS). Ownership and right of use of these biological materials are independent of the individual study and belong to the DZHK e. V. The DZHK will provide funding (as patient fees and for coordination tasks) for this DZHK biobanking (collection, management, transport) once a separate study-related application has been submitted. This DZHK biobanking is within the scope of the study to the extent that all study participants must be offered the opportunity to participate. The medical institution of the study management will be responsible for DZHK biobanking in addition to its responsibility (sponsorship) for the study in accordance with GCP.

The aim is to build a large collection of high-quality, well-documented and standardised biological materials with long-term availability that may be provided to the DZHK-internal and external cardiovascular research community for future research projects beyond the scope of an ongoing DZHK clinical study in compliance with the DZHK Use and Access Policy and GCP regulations. Using biological material collected within the scope of the DZHK biobanking project must always be requested from the DZHK Use & Access (U&A) Committee.

Study-related DZHK biobanking

Whenever required within the scope of the research purpose of the individual study or where study-related research beyond the distinct research purpose is involved, collection for the purpose of study-related biobanking is possible. The coordinating investigator is responsible for planning timepoint(s) of blood draw and detailed set composition. Details on the study-related biological materials will be documented in the DZHK LIMS. Funding will be part of the study budget. The rights of use initially belong to the main study centre for up to 2 years after completion of the study, and are solely subject to notifying the U&A Committee during this period, provided No. 3 as described below applies. After this 2-year blocking period, the rights of use of the study-related biological material are transferred to the DZHK e. V. and the material is from then on treated analogous to the DZHK biological material.

Three types of study-specific biological material are distinguished in general:

- 1) “Must have”: Biological material that is critically required to answer the question of the study and that is analysed in a timely manner. Using this material is not subject to notification during the blocking period, as the analysis is required for the study project and approved within the scope of the study application.
- 2) “Nice to have 1”: Biological material that helps answer a predefined question related to the study and whose analyses are defined. Using this material is not subject to notification during the blocking period if the analysis has been approved within the scope of the study application.
- 3) “Nice to have 2”: Biological material that helps answer a non-predefined question and whose analysis parameters are not initially known. Using this material is subject to notification during the blocking period if no distinct analysis has been mentioned in the study application.

Routine laboratory testing

Any routine laboratory samples that serve clinical diagnostics and for which biological material is directly used, with any residues being discarded, cannot be added to the DZHK collection of biological material. Parameters derived from this material will be captured in secuTrial “as data.”

¹ DZHK “basic” biobanking is from here on called “DZHK biobanking” to avoid confusion with the collection of biological material at study baseline. This material will not be available for study-specific analyses.