Application process for usage applications / notifications

Review process

1. Usage applications or notifications (for data and/or biomaterial) have to be submitted to the DZHK Transfer Office (TO).

2. A first availability check of data and/or biomaterial is carried out by the Transfer Office (TO) in parallel with the patient consent check by the Trusted Third Party (TTP).

3. The TO generates an availability statement which they forward together with the usage application to the Use and Access Committee (U&AC).

4. The U&AC will provide one of the following three recommendations in writing: (a) approval, (b) approval to certain conditions and after certain modifications or (c) rejection after reviewing the application.

Prospective applicants can screen for data and/or biomaterial which they were interested in with the feasibility tool prior to the actual application process.

No more than 10 weeks will elapse between the submission of the application and the U&AC recommendation.
Application process for usage applications / notifications

Opportunity to interpose a veto

5. The applicant, the DZHK board of directors and the respective study leader will be informed about the U&AC recommendation.

6. Within four weeks, the applicant, DZHK board of directors and study leaders have the opportunity to submit the U&AC recommendation to the RCC in case of a veto. If this does not happen, the U&AC recommendation shall enter into force.

7. After submitting the U&AC recommendation to the RCC, the RCC can uphold, modify, or make different conditions to the U&AC recommendation. The RCC is allowed to consult external experts into the decision process. The RCC decision is final.

Resubmission not possible (RCC decision is final)
Application process for usage applications / notifications
Implementation by Transfer Office and Trusted Third Party

Conclusion of data and/or material transfer agreement
Maine office with applicant

Final consent check and proband selection
Transfer Office
Trusted Third Party

Export pseudonymization
Transfer Office

Transmission of:
- Selected probands
- Requested data
- Export pseudonym
- Dispatch address
Transfer Office to Data Handling

Dispatch of secured medical data

Transmission of:
- Selected probands
- Requested materials
- Export pseudonym
- Dispatch address
Transfer Office to central LIMS

Dispatch of material by biobanks to recipient

Analysis, evaluation and publication
Applicant

Return of results
Applicant to Transfer Office