I. Preamble

One of the main ideas behind the DZHK research strategy is to carry out various multi-centric studies under harmonised framework conditions.

Without such harmonised framework conditions the DZHK would be merely another sponsor of clinical studies; subsequent comparative studies or a meta-utilisation of the data or biological specimens collected over the course of different studies would not be possible. The prerequisite for DZHK project execution on a harmonised basis is that the DZHK has ownership and disposal rights to all data entered into DZHK’s Central Data Management (ZDM) system and ownership and disposal rights to all specimen material collected in this connection. Accordingly, this Use and Access Policy applies only to data and biological specimens assessed and collected within the framework of DZHK-financed projects and to which the patients/test subjects have given their consent to the DZHK.

The purpose of this Use and Access Policy is to facilitate and promote the scientific use of data collected and specimen materials acquired within the framework of projects carried out by the German Centre for Cardiovascular Research (Deutsches Zentrum für Herz-Kreislauf-Forschung e. V.; DZHK). The DZHK aims to ensure that the collected data and specimen material is used to the greatest possible benefit for health-related research, and especially cardiovascular research.

DZHK invests considerable energy into building up a DZHK basic collection of biological specimens from all study participants, and into holding data and specimens after they have fulfilled their study purpose so that they can potentially be made available for secondary use under transparent criteria. By subjecting data and specimens to the Use and Access Policy both sides benefit – the scientist providing the data and specimens as well as the scientist applying to use them. In this process, the DZHK acts as a disinterested facilitator.

This presupposes a broad availability of data and biological specimens. The DHZK Use and Access Policy is a basic element of the central scientific infrastructure in the DZHK clinical research funding scheme. Due to the special requirements regarding protection of patients'/test subjects' rights and the high scientific value of collected data and specimen materials, applications to access data and specimen material must undergo rigorous evaluation with regard to the goals and attainable benefit. The DZHK has set up a neutral Use and Access Committee (including members of the DZHK partner institutions) to fulfil this task according to strict and transparent criteria.

This Use and Access Policy is not intended to regulate issues of utilisation and intellectual property; these will be regulated by a separate utilisation policy to be agreed with the DZHK partner institutions and, if necessary, by individual agreements based thereupon. The sale of data or specimens by the DZHK shall not take place.
Quantities of specimen material collected within the framework of DZHK projects should be measured such that additional samples will be available for future research purposes of the collecting institution (provided that the appropriate informed consent and Ethics Committee vote have been secured).

II. Introduction

Section 1: Definitions

(1) Data

In the following “data” refers to all data and results collected and generated within the various DZHK projects and research programmes; these include medical data (e.g. medical history/treatment data, results and anonymised personal and interview data), specimen data (e.g. specimen type/quality, information relating to acquisition, transport, storage, pre-analysis) and analysis data (from the analysis of specimens).

Personally identifiable information (e.g. names, addresses, dates of birth, contact information and identification numbers (e.g. health insurance, SAP-ID)) are not included.

(2) Specimens and specimen material

“Specimens” and “specimen material” refer to all biological material collected from patients/test subjects within the framework of DZHK projects. This includes, e.g., tissue, blood, serum, plasma, urine, saliva and other materials obtained therefrom, such as blood components and DNA/RNA.

(3) Data Protection Concept

“Data Protection Concept” refers to the document ‘Method description and data protection concept of the Central Data Management’ of the DZHK in its current version.

(4) Ethics Concept

The DZHK Ethics Concept includes stipulations on protecting the welfare of patients/test subjects with regard to the law on informational self-determination. The valid Ethics Concept within the meaning of this Use and Access Policy is the DZHK’s current version.

(5) Data usage

“Data usage” means the processing and use, particularly the inspection and forwarding and the statistical evaluation, of all data or parts thereof for scientific research projects, publications, presentations or for recruiting patient populations for follow-up or further studies or for the preparation of further statistical evaluations. The processing and usage of data for the purposes of controlling, monitoring, or quality assurance of data-contributing DZHK projects explicitly do not fall under the above-described data usage.
(6) Specimen usage

“Specimen usage” means the laboratory use of specimens for purposes of medical research, especially cardiovascular research, or for quality control checks.

(7) DZHK project

A “DZHK project” in the meaning of this policy is any clinical study, registry or cohort within the DZHK clinical research funding scheme which is financed fully or mainly (to at least 50% of the eligible expenditure/costs) by the DZHK. Other projects financed fully or mainly by the DZHK can, by individual agreement, be treated as being equal to DZHK projects. All data and/or specimens obtained within the framework of DZHK projects are administered by the DZHK Central Data Management (ZDM) and are subject to this Use and Access Policy.

(8) Study Leader

The leading/coordinating scientist of a DZHK project is designated “Study Leader”.

(9) DZHK-associated projects

“DZHK-associated projects” are clinical studies, registries and cohorts that are financed to less than 50 % (partially financed) or not financed by the DZHK. When a project is proposed for association the applicant and the DZHK negotiate on a case-by-case basis how the association will be arranged (e.g. application of DZHK SOPs, transfer of property and usage rights to the DZHK, integration into the ZDM, applicability of this policy) and, in cooperation with the project’s sponsoring institution, reach an agreement thereon. The goals of a DZHK-associated project must be closely aligned with the research goals of the DZHK.

(10) DZHK PI

See Section 18 of the DZHK Rules of Procedure.

(11) DZHK scientist

See Section 18a of the DZHK Rules of Procedure.

(12) DZHK Research Coordinating Committee (RCC)

See Chapter 3 of the DZHK Rules of Procedure.

(13) Research project

A “research project” is a project within the framework of a data and/or specimen usage application or a data use notification within the scope of this Use and Access Policy.

(14) Responsible Scientist

The person responsible for submitting a data and/or specimen usage application (hereinafter “Application”) is designated the “Responsible Scientist”.
(15) Contractual Partner

The “Contractual Partner” is the legal or natural person with whom DZHK concludes the usage contract according to Annex 2.

(16) Employees

“Employees” refers to all persons who are granted access to data or specimens within the framework of preparing and implementing the proposed data and specimen usage.

(17) End of the contract

The “end of the contract” within the meaning of this Use and Access Policy is the point in time specified in the usage agreement or in the usage notification at which the use of data and specimens ends.

(18) Released data

“Released data” are data released by the DZHK for usage in a research project in accordance with Section 17 for requests/applications, or according to Section 20 for data usage notifications. Data within the protection period (see Section 4 (4)) are not released.

(19) Transferred data and specimens

“Transferred data and specimens” are all data and specimens transferred to the Responsible Scientist for implementation of a research project in accordance with this Use and Access Policy. The DZHK Transfer Office or the respective bio-bank perform the transfer. Only released data may be transferred.

(20) Results

“Results” are all information gained from transferred data and/or specimens suitable for further analyses, and derived variables (new variables generated from transferred data such as categories, scores and indices, information gained from specimens, biomarkers, new specimens, etc.). Results in this meaning explicitly does not include know-how, findings or results eligible for property rights that could be exploited.

(21) ZDM independent trust agency (ZDM-THS)

DZHK’s independent trust agency (situated at the DZHK partner site in Greifswald) assumes all centralised tasks regarding personally identifying information such as the centralised storage and examination (e.g. duplicate checking) of personally identifying data, the assignment of pseudonyms to persons, the administration of information on education and study consent (consent management) including the documentation of changes to consents and of complete or partial withdrawal of agreement during the term. The personally identifying data of the trust agency are technically separated from other study data.
(22) ZDM Transfer Unit

The Transfer Unit (situated at the DZHK partner site in Göttingen) undertakes and/or supports the DZHK in the entire process of preparing data and specimens for scientific evaluation – from the selection of variables and biospecimens to the application, approval, preparation and transfer of study data to Contractual Partners, through to the reintegregation of results into ZDM, insofar as not regulated by other authorities in the DZHK statutes or in this Use and Access Policy.

(23) ZDM Clinical Data Handling (ZDM-DH)

ZDM Clinical Data Handling at the Göttingen facility includes the acquisition system for clinical research data as well as all associated data storage media and all data stored thereon. This includes, among others, all pseudonymised medical data, specimen and analysis data including the results data returned to/transfered from DZHK projects and research projects.

Section 2: Regulatory purpose

(1) The purpose of this Use and Access Policy is to ensure the transparent, efficient and preferably most productive use of data and specimens according to the basic principles of freedom of research, while at the same time respecting data protection requirements and the interests of patients/test subjects regarding protection of their personal rights as well as the interests of the institutions involved in the realisation of DZHK research projects.

(2) In addition to this Use and Access Policy, the following supplementary specifications must be observed in their currently valid version:
   (a) All data protection regulations, especially the German Federal Data Protection Act and the data protection laws of the federal states.
   (b) Guidelines on Good Scientific Practice.\(^1\)
   (c) Guidelines on Good Epidemiological Practice.\(^2\)
   (d) ICH GCP Principles of Good Clinical Practice.\(^3\)
   (e) Rules of procedure and statutes of the association of the DZHK and other internal regulations.
   (f) DZHK Data Protection Concept.
   (g) DZHK Ethics Concept.
   (h) Votes of the responsible ethics committees.
   (i) Funding stipulations.

(3) The right of the institutions collecting/obtaining data to use their collected/obtained data and results for internal research and teaching purposes remains unaffected at all times. This right is irrevocable, non-exclusive and charge-free.


\(^2\) Guidelines and Recommendations to Assure Good Epidemiological Practice (GEP) of the German Society for Epidemiology (DGEpi). Current version available on [www.dgepi.de](http://www.dgepi.de).

Section 3: Legal basis for usage

(1) The basis for any collection, processing or use of data and any withdrawal, further processing, analysis or evaluation of specimen material is the informed consent of the affected patient/test subject in accordance with the written declaration of consent.

(2) If a patient/test subject revokes his/her consent, then these data and specimens shall no longer be available from the date of revocation. This is regulated in more detail by the Ethics Concept and the Data Protection Concept.

(3) In addition, the use of data and specimen material requires notification and acceptance (Section 16 (2)) and/or approval (Section 16 (1)) by the DZHK, the conclusion of a usage agreement as well as a positive ethics vote by the responsible ethics committee (either a broadly defined approval for the DZHK project in the ethics vote or a specific ethics vote for the proposed project).

Section 4: Property and usage rights

(1) With their consent the patients/test subjects transfer ownership of samples to the DZHK. This applies regardless of a potential handover of DZHK samples to the Contractual Partner. The DZHK is thereby the owner of all samples taken from test subjects in the framework of DZHK projects. Section 6 (3) remains unaffected.

(2) With their consent patients/test subjects transfer unlimited right of use of data to the DZHK. In this connection, the institution collecting the data also transfers potential rights of use to the DZHK. This shall apply even when DZHK grants rights of use to a Contract Partner. Thereby, the DZHK has unlimited rights of use to all data, acquired within the framework of DZHK projects. Section 2 (3) and Section 6 (3) remain unaffected.

(3) All of these data and samples are saved or administered in the ZDM and are subject to this Use and Access Policy.

(4) DZHK PIs, DZHK scientists and external scientists may be granted temporary, earmarked, non-exclusive and transferable rights of use in accordance with this Use and Access Policy, provided the data and the sample material are used for purposes consistent with the objectives of the DZHK and will not compromise the interests of DZHK.

(5) Study Leaders who have contributed data and/or samples to the ZDM within the scope of a DZHK project shall - within a protection period that starts with the beginning of a project and lasts until 2 years after the end of the project term - have unlimited right of use to these project-related data and samples, provided the purpose has already been approved. During the protection period the Use and Access Committee is not permitted to otherwise release these data and samples. According to sentence (1), the use of the data/samples has to be announced in advance (see Section 20). Upon expiry of the protection
period the DZHK may release the data and samples to other research projects. Upon expiry of the protection period the Study Leader may apply to use the data and samples which he/she contributed.

(6) Study Leaders who have collected data and samples within the scope of a DZHK project which represents a register or cohort have the right to veto a release of these data and samples by the Use and Access Committee within a disposal period that starts with the beginning of a project and lasts until 2 years after the end of the project term. This also applies to data and samples not earmarked in a project application to address a specific research question and/or not reserved for specific analyses. If the Study Leader wishes to use the collected project-related data/samples within the disposal period he/she must provide the DZHK with prior notification (see Section 20). Upon expiry of the disposal period the Study Leader may apply to use the data and sample which he/she contributed beyond the scope of Section 2 (3).

(7) Data and specimens obtained within the framework of a DZHK project for the purpose of making them available for biomedical research without being earmarked for a specific project are not subject to a time limit.

(8) The DZHK shall have no obligation towards the Contractual Partner to fulfil an approved specimen/data requirement within the requested contract duration if the availability of specimen/data is limited due to factors which cannot be influenced (e.g. if the specimen turns out to have expired).

Section 5: Use and Access Committee

(1) A Use and Access Committee shall be set up, whose members shall be bound to secrecy by a secrecy agreement. Members should represent all DZHK partner sites but also cover as many different disciplines as possible. The participation of a biostatistician, a representative of the technology transfer units of the DZHK institutions (see (2)) and external representatives is required. Members are elected by the General Assembly upon proposal of the Board of Directors. The term of office is 4 years. Re-election is permitted.

(2) DZHK institutions with a technology transfer unit are required to provide the DZHK with the name of a relevant contact person. The named contact persons designate among themselves who will represent them as a member of the Use and Access Committee.

(3) The Use and Access Committee assumes the tasks assigned to it in accordance with this Use and Access Policy (see Chapter III – Application Process). It will confer as often as needed to fulfil its tasks in a timely manner. A representative from the Transfer Office and a representative from the main office should be present at consultations. The consultations are open to DZHK PIs and DZHK scientists. The Study Leader shall be given opportunity to comment. The Use and Access Committee shall decide by simple majority of its members. It may obtain opinions from external experts.
Section 6: Principles governing the use of data and specimen material

(1) The DZHK shall take appropriate security measures to guarantee the anonymity of patients/subjects and the confidentiality of their data and specimens in the case of transfer. Personally identifying information shall not be released. Under the terms of the data and specimen usage agreement, researchers undertake not to make any effort to re-identify persons whose data they have obtained and not make public or release to a third party any data that would allow a third party to re-identify individual persons.

(2) In order to use data and specimens it may be necessary to re-contact patients/test subjects, e.g. to obtain additional data or acquire additional specimens. To avoid overstretching the willingness of patients/test subjects to participate in DZHK projects, such procedures are checked carefully with regard to the significance for the expected research results and the time and effort involved for patients/test subjects. The identification of the patients/test subjects to be contacted shall be handled by an independent trustee. Details are regulated in Section 23.

(3) No commercial exploitation of the data and specimens transferred or provided by patients (see Section 4) or results obtained from the research with these data and specimens is permitted unless a separate utilisation agreement is in effect that has been agreed with the DZHK institutions.

Section 7: Usage only within the framework of application and approval

(1) Transferred data and specimens shall be used exclusively for the requested and approved purpose and only within the time frame for which the application was made and approved. Specimens shall also be used only in the laboratory specified in the usage agreement and analysis shall only use methods that save as much material as possible. Any terms and conditions contained in the approval must be observed. Any additional use of data or specimens – including the potential use of data beyond the time frame originally agreed – will require a new application.

(2) The copying or transfer of data and/or specimen material to a third party beyond the stipulations of the usage agreement is prohibited. If the use of data or specimens by a third party is desired, then a new usage application must be submitted to the DZHK. Transfer of data shall occur exclusively through the Transfer Office (see Section 21).

(3) Aggregated results (not raw data) may be transferred to the research sponsor in accordance with the stipulations of the respective cooperation agreement and taking the terms and conditions of the usage approval into consideration. The transfer of individual data or biomaterial is prohibited.
Section 8: No claim to additional funding

The granting of access to or transfer of data and/or specimens shall not infer any claim to further financial or other facilitation and support by DZHK.

Section 9: Duty to report and inform

(1) Within one year after the end of the contract, the Responsible Scientist must provide the DZHK with a final report in both written and electronic form. If the data are used to prepare a scientific publication, it will be sufficient to present the manuscript to be published. The Board of Directors shall treat all information obtained in this connection as confidential.

(2) The main office of the DZHK must be informed about all publications resulting from the use of the data and specimens. One copy of the printed version (alternatively: digital version) must be submitted to the main office.

(3) The Responsible Scientist shall inform the DZHK of any known errors in the data.

Section 10: Re-transfer and administration of project results

(1) Once the analysis has been completed and the data prepared the Responsible Scientist shall make the results available to the DZHK in their entirety and in suitable electronic form no later than one year after the end of the contract.

(2) In doing so, care must be taken to provide a sufficient, self-explanatory documentation of the results and the evaluations, including the evaluation programs (and versions) used to generate the results. In addition, the documents on the materials, methods, protocols and (statistical) methods used as well as observations and deviations must be made available to DZHK in electronic form. The format of the results that are to be transferred electronically must be coordinated with the Transfer Office. Care must be taken that the format is one that can be read with standard software. It is particularly important that the information be broken down into the smallest sensible units and that accessibility is ensured.

(3) The results will be integrated into the data storage of the central data management system (ZDM). For delivery of the results to other scientists, a protection period of two years after end of the data and specimen utilisation contract is valid unless otherwise agreed in the contract. After the end of this protection period, other scientists may apply for a transfer of the results in accordance with the rules on the utilisation of data set down herein. The Contractual Partner, from whose application the results originate, shall be informed about the transfer. The Contractual Partner who applied for and received the right to utilise the results will be informed about the participation of the Contractual Partner whose application was the originator of the results, to proceed in accordance with the Good Scientific and Good Epidemiological Practice. This is regulated in detail in Section 11.
The duty to store the data provided by the DZHK and the results retransferred to the DZHK, e.g. in the context of publications, will be exercised by the Transfer Office. The Transfer Office shall ensure that the submitted data and the retransferred results and data are available later for inspection and subsequent analyses (see recommendation 6.1 of the Guidelines for Good Epidemiological Practice²).

The Responsible Scientist shall store all (paper and digital) original documents on the analyses (incl. the materials used, applied methods, protocols (statistical processes) and observations, deviations) as well as results and evaluation programs for a period of at least 10 years.

Section 11: Right to publish and right to non-commercial use of the results

(1) The rules of Good Scientific Practice³ shall apply to all publications that use the data, specimen material or results.

(2) Written publications that are partially or wholly based on data or specimen material or results transferred by the DZHK must contain a statement that these were made available by the DZHK. DZHK PIs or scientists who have participated in generating or preparing the data or the specimens must be named in an appropriate manner. Details are regulated in the publication rules of the DZHK.

(3) According to the second sentence of Section 10 (3), the Contractual Partner and/or the Responsible Scientist shall retain the exclusive right to use and publish the results obtained for the usage specified in the application until the protection period has expired. During the protection period, any usage by the DZHK, its members or by third parties may take place only upon written approval by the Contractual Partner.

(4) Results and data may only be published in a form that does not allow the personal identity of test subjects/patients to be traced.

Section 12: Deletion of data and return of unused specimen material

(1) The Contractual Partner shall delete all transferred data no later than 5 years after the end of the contract, unless an application for extension has been filed and approved prior to the end of this period (analogous to Section 15 et seq.). The Transfer Office must be informed about the deletion without delay.

(2) Once the contract period has ended, any specimen materials not used by the Contractual Partner for the intended purposes must be made available to the DZHK without delay. This is to take place in coordination with the Transfer Office and the relevant decentralised bio-banks and in such a way that permits the further use of the remaining specimen material. Should that not be possible, then, in coordination with the Transfer Office and the relevant bio-banks, the unused specimen material must be destroyed. The Transfer Office must be informed in writing about the return / destruction of the unused material.
Section 13: Liability of the DZHK

The liability of the DZHK is regulated in the individual license agreement.

Section 14: Responsibility and liability of the Contractual Partner and/or the Responsible Scientist

The responsibility and liability of the Contractual Partner and/or the Responsible Scientist are regulated in the individual license agreement.

III. Application procedure

Section 15: Principles of the application procedure

(1) The following application procedure will be implemented for the utilisation of the data and specimens.

(2) Within the meaning of broad public benefit, access to data and specimen material can be granted to every scientist in the sense of a wide profit for the general public for medical research purposes that are in the public interest, especially for research into cardiovascular diseases.

(3) Applications from scientists working in commercial enterprises shall only be accepted if the company has no direct economic interest and if the use of the data or specimens is regulated by a corresponding agreement (see Section 6 (3)).

Section 16: Form and content of the application/notification

(1) All use of data/specimen material requires prior authorisation by the DZHK. Applications for authorisation/data usage notification must be made to the DZHK via the Transfer Office. This should be done using the form in Annex 1, which requests all information relevant for the authorisation in accordance with (2).

(2) The application contains the following information: Responsible Scientist, Contractual Partner, other participants (e.g. cooperation partners), function of the participants within the research project, the title of the project, proposed project period, project objective, scientific background, description of the project, justification of feasibility, material and human resources available for carrying out the project, details of the required data and the specimens (type of data/specimen, origin (which patients/test subjects), quantities of specimens required, reason for the specimen quantities required), information regarding the financing of the research project, information regarding the need to re-contact patients/test subjects and, where applicable, the positive evaluation of the responsible ethics commission (see Section 3 (3)). Applications for usage of specimen material must also contain information pertaining to the parameters of the specimens to be determined and the method of analysis to be used.
Section 17: Examination of the application, positive quality control of the project

(1) The Transfer Office passes on submitted applications and notifications together with a statement regarding availability to the Use and Access Committee so that it can prepare for its meetings. The Use and Access Committee should come to a decision not more than ten weeks after receiving an application/notification.

(2) The Use and Access Committee examines applications according to the following criteria:
   (a) Identity and scientific reputation of the applicant (Responsible Scientist).
   (b) The scientific justification for the described project (scientific concept including reason for number of cases and analysis strategy) is convincing.
   (c) The application is consistent with the scientific objectives of the DZHK.
   (d) Compliance with legal and ethical standards as well as the rules of this Use and Access Policy.
   (e) (Expected) availability of a sufficiently large amount of data and specimens.
   (f) The application is consistent regarding the requested data/specimens for the proposed evaluations/analyses.
   (g) The objective of the evaluation/analyses can be achieved with the resources described in the application.
   (h) The application is consistent with the collaborative character of the DZHK (priority use of data/specimens by DZHK PIs and DZHK scientists).
   (i) Applicants from the circle of participating scientists always have priority over third-party applicants.
   (j) Should renewed contact to patients/test subjects become necessary in order to carry out the research proposal, the application can be delayed until the next follow-up monitoring/follow-up examination or a cooperation with other applications that require that patients/test subjects be re-contacted may take place (see also Section 6 (2)).
   (k) In the event of an overlap with other data usage applications or notifications (whether requested, approved or completed): The objective of the joint work and the mediation of cooperation if there are several parties interested in the same type of research question.
   (l) The informed consent declaration provided by the patients/test subjects complies with the requested usage.
   (m) The financing concept for implementing the proposed research project is plausible.

(3) If an application to utilise specimens is filed, the following additional criteria are taken into consideration to ensure optimal utilisation of the limited amount of specimens:
   (a) The scientific justification for the use of the requested specimen material, the selection of the biomarkers to be analysed and the method of analysis (including information regarding measuring accuracy and precision and validity and reliability of the biomarkers, if present) is convincing.
   (b) Proportionality of the specimen material to be released to the scientific significance of the objective of the use of the specimen and to the total amount of available specimens.
   (c) Obligation of the applicant to use the specimen material economically and efficiently.
   (d) Consideration of existing similar biomarker determinations.
(e) Minimisation of the number of thawing and freezing cycles to which specimens are subjected.

(4) When applying to use specimens a representative of the respective bio-bank must provide an opinion. The applicant has the right to be heard.

(5) After examining the application, the Use and Access Committee will provide one of the following three recommendations in writing:
   (a) The application should be approved.
   (b) The application may only be approved subject to certain conditions and after certain modifications have been made.
   (c) The application should be rejected.

(6) In each case, the recommendation must be justified in writing and any conditions or modifications must be defined. Utilisation must not be unreasonably withheld. One possible condition is that the work must be carried out jointly with other applicants/projects working on the same or very similar questions and that the methods be jointly harmonised. Another possible condition is that the specimens be used only at a later point in time if this would mean a more efficient use of the specimens can be achieved.

(7) The Applicant, the Board of Directors of the DZHK and the respective Study Leader will be informed about the recommendation issued as per Section 17 (5). Within a period of four weeks any of these three may exercise their right to request that the application be presented to the RCC of the DZHK for a decision. If this is not done, the recommendation will become effective after the four-week period has passed. The Study Leader only has the right to veto a proposed usage in the case of specimens which are obtained for a specific project in the framework of a register or cohort study and which are subject to a disposal period (see Section 4 (5)).

(8) If an application is presented to the RCC it can confirm, modify or impose different conditions to the recommendation issued under Section 17 (5). The RCC may consult third-party experts. Its decision is final.

(9) If the approval is subject to conditions or can only be approved after certain modifications have been made, the applicant will be asked to rewrite the application accordingly and to present it anew.

(10) If an application is approved, the Transfer Office will be tasked with the further processing of the procedure. To make the approval procedure more transparent abstracts of approved applications which allow the use of data and specimens with their respective current status (approved/completed/results published) are to be published on the DZHK website.
Section 18: Denial of utilisation approval

(1) Irrespective of whether the application fundamentally qualifies for approval, utilisation approval may be denied if the Responsible Scientist or another employee has violated this Use and Access Policy in a previous case and to a significant extent.

(2) A significant violation exists, in particular, if:
   (a) Access rights according to Section 4 were disregarded.
   (b) The previous utilisation exceeded the permissible scope set out in Section 7.
   (c) The duty to report in accordance with Section 9 was not complied with, despite warning.
   (d) Results were not made available as per Section 10.
   (e) Publication rules were violated (Section 11).
   (f) Transferred data was not deleted or residual specimen material was not returned or destroyed (Section 12).

Section 19: Data and specimen utilisation contract

(1) The prerequisite for the transfer of data and/or specimens following approval of an application is the conclusion of a data and/or specimen utilisation contract (hereinafter: utilisation contract). The Contractual Partner agrees in this contract to comply with the terms and conditions of usage. The utilisation contract specifies, in particular:
   (a) Start and end of the contract.
   (b) The data and/or specimens to be made available for the project (quality and quantity).
   (c) The duty to report and inform according to Section 9 and to return the results as set out in Section 10.
   (d) The latest date for returning unused specimens.
   (e) The latest date for deleting the data that was provided.
   (f) Other conditions and stipulations.

(2) The daft contract to be used is attached as Annex 2 to this Use and Access Policy.

Section 20: Data usage notification

(1) The Use and Access Committee examines the proposed data usage with regard to whether the prerequisites set out in Section 16 (2) are fulfilled and whether the criteria of Section 17 (2) d) and k) are met and, in the case of Section 17 (1) k), also in order to avoid the establishment of internal subsets of data for addressing questions which are currently being addressed across projects or which are to be processed in the near future.

(2) A specimen usage notification is possible only in the cases mentioned in this Use and Access Policy.
After examining the notification, the Use and Access Committee provides the Board of Directors of the DZHK with one of the following recommendations in writing:

(a) There are no objections to the use of the data.
(b) The data can be used only under certain conditions.
(c) The use of the data should be prohibited.

In each case, the recommendation must be justified in writing, and any conditions or modifications must be defined. In addition, the procedure set out in Section 17 (7) and (8) shall apply.

If the utilisation of the data is not prohibited, the abstract and the current status of the project as well as an approved data utilisation application will be published on the DZHK website.

The Contractual Partner is responsible for the implementation of appropriate measures within the meaning of Section 6 (1). The right to use the data is non-exclusive and non-transferable. The regulations set out in Section 9 and Section 10 apply correspondingly.

IV. Transfer of data or specimens

Section 21: Transfer of data

Once the utilisation contract has been concluded, the Transfer Office will prepare the data in accordance with the following points (2) to (6) into one data set to be transferred to the Responsible Scientist while observing the Data Protection Concept.

For each patient/test subject for whom data are incorporated into the data set to be transferred, a further check is carried out to determine whether the existing declaration of consent permits the utilisation of this data.

Using suitable measures, data that might identify the person or that might lead to a person being identified will not be made available (see (5), (6)). All identifiers required for data linking will be replaced by pseudonyms set up specifically for the project. The link between the original identifiers and the project-specific pseudonyms will be held by the independent trustee and will not be transferred to the Contractual Partner.

Any birth dates that may be included in the data set shall be replaced by age categories with the accuracy that the project requires.

If the data set to be transferred is to contain geo-coding of address data, then this information will be altered in cooperation with the Transfer Office and the Trust Agency by adding random numbers from a specified interval to the respective x and y coordinates in such a way as to prevent identification of the correct address.
(6) If required, the data set shall be further modified to reduce the risk of re-identification (e.g. by replacing certain dates).

(7) The Transfer Office shall coordinate and carry out the technical details of the data transfer in consultation with the Responsible Scientist.

**Section 22: Transfer of specimens**

In addition to the regulations set out in Section 21 for the transfer of specimens, the following provisions shall apply:

1. On the basis of the utilisation contract, the Transfer Office will prepare a table that provides information on the selection of the patients/test subjects in anonymised form and the amount of the required specimen material.

2. The specimen material will be transferred only to a recipient named by the Contractual Partner who, as a rule, is the Responsible Scientist.

**Section 23: Personally identifying data, contacting test subjects**

The identification of patients/test subjects (for example, to make a re-identification possible) shall only be possible after authorisation by the RCC and shall take place exclusively via the independent trustee agency. Patients/test subjects may only be contacted by the participating DZHK PI or the DZHK scientist who is maintaining the contact with the patient/test subject. This contact may, however, be coupled with a request for the patient/test subject to consent to the transfer of contact data to the Responsible Scientist and to consent to contact by the Responsible Scientist for the exclusive purpose of carrying out the approved project. In every case the procedure described above requires the informed consent of the concerned patient according to Section 3 (1).

**Section 24: Reimbursement of costs**

(1) The decentralised bio-banks, the Central Data Management or the DZHK e.V. may incur additional material and/or staffing costs in connection with the supply, preparation and transfer of data/specimens. As a rule, such costs shall be borne by the Contractual Partner. Details are to be regulated in the utilisation contract as needed.

(2) There will be no sale of data or specimens.

V. Legal consequences in case of infringements

**Section 25: Revocation or restriction of usage rights**

(1) The DZHK may revoke, in part or in full, the usage permit granted to the Contractual Partner in the case of any violation of this Use and Access Policy and/or of the provisions of the utilisation contract or the conditions imposed regarding the use of the data.
(2) This applies in particular, but not exclusively, if:
   (a) The rights of disposal of DZHK as per Section 4 are disregarded.
   (b) The utilisation has exceeded the permissible scope set out in Section 7.
   (c) The duty to report and inform as per Section 9 is not complied with, despite warning.
   (d) The results are not made available as per Section 10.
   (e) The rules for publications are violated (Section 11).
   (f) Data protection stipulations are disregarded.

(3) In the case that a usage permit is revoked, all utilisation of the transferred data and/or specimens must cease immediately. The unused specimens must be returned immediately to the respective decentralised bio-bank. The Transfer Office must be informed about the results. Restrictions of the usage rights shall be agreed on by means of an addendum to the utilisation contract, which the Contractual Partner is obligated to conclude.

(4) Further claims of the DZHK, particularly in the case of culpable violations by the Contractual Partner, shall remain unaffected.

(5) The decision to restrict or revoke the usage permit shall be made by the RCC upon recommendation of the Use and Access Committee.

VI. Final provisions

Section 26: Entry into force and interim arrangements

The DZHK General Assembly and the Commission of Sponsors of the DZHK have agreed on this Use and Access Policy; it comes into effect on 12th August 2014.

Section 27: Acknowledgement

DZHK wishes to express its gratitude to the National Cohort e.V. for providing its Use and Access Policy as a textual basis for the development of the present DZHK Use and Access Policy.

VII. Annexes

Annex 1: Application/notification form

Annex 2: Draft of a data and specimen utilisation contract