DZHK e. V. ‘Use and Access Policy’
for the use of DZHK data and biological specimen
Publisher and responsible:
Deutsches Zentrum für Herz-Kreislauf-Forschung e. V.
DZHK-Geschäftsstelle
Potsdamer Str. 58
10785 Berlin, Germany

Version:
V 1.1

Contact:
Tel.: +49 (0)30 3465 529 10
Email: use.access@dzhk.de
www: https://dzhk.de/forschung/dzhk-sammlung/daten-und-probensammlung/
Contents

I.  Preamble ............................................................................................................................................. 4
II.  Introduction ...................................................................................................................................... 5
  Section 1.  Definitions .......................................................................................................................... 5
  Section 2.  Regulatory purpose ............................................................................................................. 10
  Section 3.  Legal basis for usage .......................................................................................................... 11
  Section 4.  Property and usage rights .................................................................................................. 12
  Section 5.  Use and Access Committee (UAC) .................................................................................. 13
  Section 6.  Principles governing the use of data and biological specimen within secondary use projects 13
  Section 7.  Usage only within the framework of usage application and their approval ....................... 14
  Section 8.  No claim to additional funding .......................................................................................... 14
  Section 9.  Duty to report and inform .................................................................................................. 14
  Section 10. Re-transfer and administration of secondary use project results ..................................... 15
  Section 11. Right to publish and right to non-commercial use of the results of secondary use projects 15
  Section 12. Deletion of data and return of unused .............................................................................. 16
  Section 13. Liability of the DZHK ...................................................................................................... 16
  Section 14. Responsibility and liability of Contractual Partner and/or Responsible Scientist ............ 16

III.  Application procedure ..................................................................................................................... 16
  Section 15. Principles of the application procedure ............................................................................. 16
  Section 16. Form and content of the usage application and notification ............................................. 17
  Section 17. Examination of application, positive quality control of the secondary use project ........... 17
  Section 18. Denial of utilisation approval ............................................................................................. 19
  Section 19. Material (and data) transfer agreement (MTA) ................................................................ 20
  Section 20. Usage Notification .......................................................................................................... 20

IV.  Transfer of data or biological specimen .......................................................................................... 21
  Section 21. Transfer of data ............................................................................................................... 21
  Section 22. Transfer of biological specimen ......................................................................................... 21
  Section 23. Person-identifying information, contacting study participants ......................................... 22
  Section 24. Reimbursement of costs .................................................................................................... 22

V.  Legal consequences in case of infringements .................................................................................. 22
Section 25. Revocation or restriction of usage rights ................................................................. 22

VI. Final Provisions .................................................................................................................. 23

Section 26. Entry into force and interim arrangements ............................................................ 23

Section 27. Acknowledgements .............................................................................................. 23

VII. Annexes .......................................................................................................................... 23
I. Preamble

One of the main ideas of the DZHK research strategy is to invest in a large number of (predominantly) multicentre studies with uniform, harmonised framework conditions.

Without such harmonised framework conditions, the DZHK would merely sponsor clinical studies; subsequent comparative studies or a meta-utilisation of the data or biological specimen collected over the course of different studies would not be possible. The prerequisite for DZHK study execution on a harmonised basis is that the DZHK has ownership and disposal rights to all data entered into DZHK’s clinical research platform and ownership and disposal rights to all biological specimen collected there. Accordingly, this Use and Access Policy applies only to data and biological specimen assessed and collected within the framework of DZHK studies and to which the study participants 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 biological specimen acquired within the framework of DZHK studies 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 biological specimen is used to the greatest possible benefit for health-related research, and especially cardiovascular research.

The Use and Access Policy was developed on the basis of the first version of the NAKO e.V. Use and Access Policy for the NAKO Health Study. In the course of the cooperation between the DZHK and the Network University Medicine (NUM), the DZHK Use and Access Policy was provided as a basis for the development of the NUM Use and Access Policy, and the NUM Use and Access Policy was developed from it. In turn, the findings from this cooperation flowed into the development of version 1.1 of the DZHK Use and Access Policy.

DZHK invests considerable energy into building up a DZHK collection based on basic biobanking and basic data set from all study participants, and into providing study-specific data sets and study-specific biological specimen after they have fulfilled their study purpose as well for secondary use under transparent criteria. By subjecting data and biological specimen to the Use and Access Policy both sides benefit – the scientists providing the data and biological specimen as well as the scientists applying to use them. In this process, the DZHK acts as a disinterested facilitator.

This presupposes a broad availability of data and biological specimen. The DHZK Use and Access Policy constitutes a basic element of DZHK funding of clinical research. Due to the special requirements regarding protection of study participants and the high scientific value of collected data and biological specimen, applications to access data and biological specimen must undergo rigorous evaluation with regard to the goals and attainable benefit. The DZHK has set up a neutral Use and Access Committee (referred to as “UAC” in this document) 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 biological specimen by the DZHK shall not take place.
Quantities of biological specimen collected within the framework of DZHK studies should be measured so cautiously that additional biological specimen 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 obtained within the various DZHK studies and secondary use projects (corresponding to the DZHK collection); these include clinical data (e.g. medical history/treatment data, findings and anonymised personal and interview data), biological specimen data (e.g. type/quality, information relating to acquisition, transport, storage, pre-analysis), imaging data, and analysis data (from analysis of biological specimen). Personal identifiable information (e.g. names, addresses, dates of birth, contact information and identification numbers (e.g. health insurance, SAP-ID)) are not included.

(2) Biological specimen
“Biological specimen” refers to all biological material obtained from study participants within the framework of DZHK studies and within the framework of other biological specimen collections funded by the DZHK. This includes, e.g., tissue, blood, serum, plasma, urine, saliva and other materials obtained therefrom, such as blood components and DNA/RNA.

(3) Results
Results are all information and derived variables obtained from transferred data and biological specimen as well as information and variables suitable for further evaluation (new variables generated from transferred data such as categories, scores and indices; information obtained from biological specimen, new biological specimen, etc.) that arise during the implementation of a secondary use project. Results in this sense are in particular not "know-how", findings or results capable of being protected by property rights which are to be exploited.

(4) Studies at the DZHK

(4a) DZHK study
DZHK studies recognise the utilization of the DZHK Use and Access Policy, use the DZHK Clinical Research Platform, and implement demands of the DZHK internal harmonisation process in a binding manner. Studies fully or predominantly funded by the DZHK within the framework of the flexible funds are obligatory DZHK studies. The term DZHK study also includes registries and cohorts.

(4b) Studies partially financed by the DZHK

---

1Definitions are shown in italics at the relevant points in the text.
Studies partially funded by the DZHK are not subject to the DZHK Use and Access Policy, do not use the DZHK Clinical Research Platform and therefore do not participate in the DZHK Use and Access processes. These studies are funded proportionally by the DZHK.

(4c) Studies associated with the DZHK

Studies associated with the DZHK receive non-material support from the DZHK and are subject to regulations in the area of clinical research, which does not include funding. They do not use the DZHK Clinical Research Platform, are not subject to the DZHK Use and Access Policy and therefore do not participate in the DZHK Use and Access processes.

(5) DZHK Clinical Research Platform

The Clinical Research Platform provides a data platform with centralised acquisition and an access to data and biological specimen, ethics and data protection. This platform enables and supports standardised data capturing in multicentre national and international clinical trials with the aim of standardising data and biological specimen acquisition between all DZHK studies, establishing sustainable repositories that store the data and biological specimen, and making the inventory of these repositories available to the scientific community in accordance with the FAIR (Findable, Accessible, Interoperable and Reusable) guidelines and these rules of use. The actual systems of this platform include the Ethics Project, the Independent Trusted Third-Party Office, the Data Management, the Transfer Office, the Laboratory Information Management System (DZHK-LIMS), and the Image Data Management System (DZHK-IDMS). All projects are closely related to each other. All systems meet the highest international standards in terms of ethics, IT, and data security and provide technical, organisational, and structural support.

(5a) Data Protection Concept

The document "Procedural Description and Data Protection Concept of the Clinical Research Platform" from the DZHK in its current version is referred to as the Data Protection Concept.

(5b) Ethics Concept

The DZHK Ethics Concept includes stipulations on protecting the welfare of study participants 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.

(5c) Independent Trusted Third-Party Office

The Independent Trusted Third-Party Office guarantees that personal data is pseudonymised and that medical data can be linked to personal data. It also centrally monitors compliance with the consent forms of study participants on an ongoing basis. Close cooperation between the Independent Trusted Third-Party Office and the Transfer Office enables a trustworthy and pseudonymous release of data and biological specimen (use and access).

(5d) Ethics project

The ‘Ethics project’ is part of the Clinical Research Platform and works closely with all other sub-projects of this platform as well as with the DZHK studies. The Ethics Project supports the harmonisation of the contents of the Informed Consents of the individual DZHK studies, takes the lead in drawing up the
present DZHK Ethics Concept, which contains the models for patient information and consent forms, and updates this on an ongoing basis. This creates the basis for all use and access processes.

(5e) Data Handling

The Data Handling archived collected clinical data from a DZHK study in an IT system (based on the SecuTrial software). This enables study-independent data standardisation and overarching data quality control. The Data Handling also includes all pseudonymised clinical data, biological specimen and analysis data, including the results data returned/transmitted from DZHK studies and secondary use projects.

(5f) Transfer Office

The Transfer Office processes usage applications and notifications in the sense of preparing availability checks on data and biological specimen (including by querying the current consent status at the Independent Trusted Third-Party Office) and thus supports the work of the UAC. After the release of usage applications or notifications, the Transfer Office makes the corresponding data and/or the biological specimen available to the applicants as agreed in the MTA and later reintegrates the results from secondary use projects into the DZHK's Data Handling. Only the Transfer Office is authorised to request data and/or biological specimen releases.

(5g) Biobanking and Laboratory Information and Management System (LIMS)

Decentralised biological specimen collection means that each DZHK Clinical Study Unit or study centre maintains a DZHK biobank according to DZHK standards. Each DZHK study includes a cross-study, purpose-independent, prospective biological specimen collection project, known as “basic biobanking”. For this, study participants are asked to donate a defined set of biological specimens. The DZHK is the owner of the decentral collected and stored biological specimen that are available to the research community worldwide (“DZHK Collection”). All biological specimen data is centrally recorded, stored and managed in a laboratory information and management system (LIMS).

(5h) Imaging and Image Data Management System (IDMS)

The task of the Image Data Management System (IDMS) includes the central storage and analysis of image data such as e.g. echocardiograms. This eliminates the need to forward data carriers to the respective evaluation centre (CoreLab), as image data is sent online directly to a study-specific CoreLab, which evaluates the data according to uniform criteria. CoreLabs ensure that image data is analysed in a standardised manner by experienced experts within one hour. This increases the quality and scientific significance of the analyses.

(6) Secondary use of data and biological specimen

Secondary use of data means the processing and use, in particular inspection and forwarding, as well as the statistical analysis of all data or a subset thereof for scientific research projects, publications, lectures or for the recruitment of collectives of study participants for follow-up studies or for the preparation of further statistical evaluation work. The processing and usage of data for the purposes of controlling, monitoring, or quality assurance of data-contributing DZHK studies explicitly do not fall under the above-described secondary use of data.
Secondary use of biological specimen means the laboratory use of biological specimen for purposes of medical research, especially cardiovascular research, or for quality control checks.

(6a) DHZK collection

The DHZK collection comprises clinical data, biological specimen including associated biological specimen data, and image data collected in DHZK studies and other DHZK-funded data and biological specimen collections after consent of study participants. The basis of the collection consists of the basic dataset and the biological specimen incl. associated biological specimen data from the basic biobanking. After the expiry of the protection period of DHZK studies according to Section 4(5), study-specific clinical data and biological specimen including associated biological specimen data as well as tissue samples including associated tissue sample data shall be submitted to the collection.

(6b) Basic Biobanking

In DHZK studies, study participants - provided they have consented - have a fixed, “baseline” biobanking set drawn at time zero (before any intervention). These samples are assembled independently of and in addition to any biomaterial needed for the study implementation. Details of the DHZK biological specimen are documented in the DHZK Laboratory Information and Management System (LIMS). Ownership and rights of use of these biological specimens lie with the DHZK.

(6c) Basic data set

The basic data set is a minimum clinical data set that is recorded of study participants in the DHZK studies on medical history (in reduced form).

(6d) Decentralised biobank

Consists of several biobank locations at the DHZK Clinical Study Units, which are equipped with standardised devices to collect and store data and biological specimen from DHZK studies in a comparable and standardised manner.

(6e) Secondary use project

A secondary use project is a project within the scope of a usage application or a notification within the meaning of these Regulations and concerns the secondary use of data and/or biological specimen (see Section 1 (5)) from the DHZK collection.

(6f) Usage application

Scientists apply for data and/or biological specimen from the DHZK collection according to Section 16(2).

(6g) Usage Notification

Principal investigators have an unrestricted right to use the collected study-specific data and biological specimen during the protection period Section 4(4), the use of which must be reported to the UAC in advance in accordance with Section 16(3).

(6h) Data catalogue
It is important that the data and biological specimen collected in DZHK studies are seen and used by the global research community. To provide the relevant information, the Data Catalogue provides a detailed description of the data and biological specimen captured in the Clinical Research Platform (what is captured), including the associated metadata (how it is captured), in accordance with the internationally recognised FAIR principles. Data catalogue (https://dzhk.de/forschung/dzhk-sammlung/datenkatalog/) shall be accessible via the DZHK website.

(6i) Feasibility Explorer (availability check)

The Feasibility Explorer is the tool that enables researchers to gain an overview of the data and biological specimen in the DZHK collection that are on offer for secondary use projects (https://dzhk.de/forschung/dzhk-sammlung/verfuegbarkeitscheck/). The Feasibility Explorer supports researchers by filtering data and biological specimen for a specific collective that may answer their individual research project question. Selected filter settings can be transferred directly to the usage application. Only cleaned data from participants with valid consent will be used.

(6j) Released data and biological specimen

Data and biological specimen are released by the DZHK in accordance with Section 17 upon usage application, or in accordance with Section 20 upon usage notification, for use within a use project by the UAC.

(6k) Transferred data and biological specimen

Transferred data and biological specimen are all data and biological specimen that have been approved and released to responsible scientists for the implementation of a usage project in accordance with these usage regulations.

(6l) Material (and data) transfer agreement (MTA)

The transfer of biological specimen and/or data from the DZHK collection for a secondary use project is subject to the conclusion of a material (and data) transfer agreement (MTA). This specifies principles such as project title, contractor, data and biological specimen recipient, timeline and special conditions. Among other things, the respective usage application or the respective usage notification must always be attached. Biological specimen may only be released by a decentralised biobank if the Transfer Office requests this and provides the legally signed MTA including attachments.

(6m) End of contract

The end of the contract within the meaning of these Use and Access Policy is the point in time specified in the MTA at which the use of data and/or biological specimen ends.

(7) People and committees
(7a) Principal investigator

The main lead of a DZHK study is hereinafter referred to as ‘Principal investigator’.

(7b) Responsible scientists
Responsible scientists are applicants who are listed accordingly in the usage application or in the usage notification (Annex 1 or 2).

(7c) Contractual partners

Contractual partners are legal entities or natural persons who conclude the Material Transfer Agreement (hereinafter referred to as ‘MTA’) with the DZHK in accordance with Annex 3.

(7d) Contributors

Contributors are all persons who have access to data or biological specimen within the framework of secondary use projects in the preparation or implementation of the requested data and biological specimen utilisation.

(7e) DZHK-PI

See Section 19b of the DZHK Rules of Procedure as amended.

(7f) DZHK scientists

See Section 18b of the DZHK Rules of Procedure as amended.

(7g) DZHK Research Coordinating Committee (RCC)

See Chapter 3 of the DZHK Rules of Procedure as amended.

(7h) Clinical Study Group (CSG)

See Section 21a of the DZHK Rules of Procedure as amended.

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 biological specimen according to the basic principles of freedom of research, while at the same time respecting data protection requirements and the interests of study participants regarding protection of their personal rights as well as the interests of the institutions involved in the realisation of DZHK studies. Furthermore, Section Section 4 and Section Section 10 regulate principles for DZHK studies.

(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 GDPR, the German Federal Data Protection Act and the data protection laws of the federal states.
(b) Guidelines on Good Scientific Practice
(c) Guidelines on Good Epidemiological Practice
(d) ICH GCP Principles of Good Clinical Practice
(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 (funding contracts or supplementary agreement including annexes)
(j) DZHK Publication Policy

(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.

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 biological specimen is the informed consent of the study participants affected in accordance with the written declaration of consent.

(2) If study participants revoke their consent, then these data and biological specimen shall no longer be available from the date of revocation. An exception can be the anonymised use of data and biological specimen, provided that the study participants have explicitly agreed to this procedure. This is regulated in more detail by the Ethics Concept, the Data Protection Concept, and the study-specific declaration of informed consent.

(3) In addition, the use of data and biological specimen requires usage notification and acceptance (Section 16 (1) and (3)) and/or approval of an usage application (Section 16 (1) and (2)) by the DZHK, the conclusion of an MTA as well as a positive ethics vote by the responsible ethics committee (either a broadly defined approval for the DZHK study concerned in the ethics vote, or a specific ethics vote on the secondary use project), which must be available to the UAC at or before the release of data and biological specimen.

(4) The DZHK is not obliged to fulfil an approved biological sample/data request within the requested contract period if the availability of biological specimen/data is limited due to factors beyond its control (e.g. the biological specimen turns out to have expired).

References:
3 Guidelines and recommendations for safeguarding Good Epidemiological Practice (GEP) of the German Society for Epidemiology (DGEpi). Current version available at www.dgepi.de
Section 4. Property and usage rights

(1) With their consent the study participants transfer
   (a) ownership of biological specimen to the DZHK. This applies regardless of a potential handover of DZHK biological specimen to the Contractual Partner. The DZHK is thereby the owner of all samples taken from test subjects in the framework of DZHK studies and their use which has not been revoked by study participants. Section 6 (3) remains unaffected.

   (b) 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. Thereby, the DZHK has unlimited rights of use to all data acquired within the framework of DZHK studies. Section 2 (3) and Section 6 (3) remain unaffected.

(2) All of these data and biological specimen are saved or administered in the Clinical Research Platform and are subject to this Use and Access Policy.

(3) 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 biological specimen are used for purposes consistent with the objectives of the DZHK and do not compromise the interests of DZHK.

(4) Principal investigators who have contributed study-specific data and/or biological specimen to the Clinical Research Platform within the scope of a DZHK study, that is neither a register nor a cohort, shall - within a protection period that starts with the beginning of a project and lasts administratively until 2 years after the end of the project term - have unlimited, non-transferable, non-sublicensable right of use to these project-related data and biological specimen, provided the purpose has already been approved by the CSG/RCC. During the protection period the UAC is not permitted to otherwise release these study-specific data and biological specimen; excluded from this stipulation are the basic dataset and biological specimen from the basic biobanking, which are collected for the DZHK collection. According to sentence (1), the use of the data/biological specimen has to be announced in advance (see Section 20), unless such use is in accordance with the study objective set out in the approved study application. Upon expiry of the protection period the DZHK may transfer the study-specific data and biological specimen in the DZHK collection and release them to secondary use projects. Upon expiry of the protection period the Principal investigator must apply to use the data and biological specimen which they contributed via a usage application.

(5) Principal investigators who have collected data and samples within the scope of a DZHK study which represents a register or cohort have the right to veto a release of study-related data and biological specimen collected by the UAC within a disposal period that starts with the beginning of a project and lasts until 2 years after the administrative end of the project term; excluded from this are the basic dataset and the basic biobanking, which is collected for the DZHK collection. This also applies to data and biospecimen not earmarked in a study application to address a specific research question and/or not
reserved for specific analyses. If the Principal investigator wishes to use the collected study-related data/samples within the disposal period they must provide the DZHK with prior usage notification (see Section 20). Upon expiry of the disposal period the Principal investigator may beyond the scope of Section 2 (3) apply with a usage application to use the data and biological specimen which they contributed.

Data and biological specimen obtained within the framework of a DZHK study for the purpose (basic biobanking and basic datasets) of making them available for biomedical research via the DZHK collection without being earmarked for a specific project are not subject to any time limit nor any right to veto. 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 biological specimen turns out to have expired).

Section 5. Use and Access Committee (UAC)

(1) A UAC 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 ethics project, 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 appointment of the Board of Directors. It is possible to appoint a proxy of the members designated by the General Assembly to represent the respective UAC member in meetings of the UAC. The decision on a usage application or a usage notification remains the sole responsibility of the member of the UAC. The duration of the UAC term shall be four years. Members may be re-elected. As a rule, no one should be a member for more than two full terms.

(2) DZHK institutions with a technology transfer unit can 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 UAC.

(3) The UAC 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 DZHK 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 UAC shall decide by simple majority of its members present. It may obtain opinions from external experts.

Section 6. Principles governing the use of data and biological specimen within secondary use projects

(1) The DZHK shall take appropriate security measures to guarantee the anonymity of study participants and the confidentiality of their data and biological specimen in the case of transfer. Personally, identifying information shall not be released. Under the terms of the MTA, researchers undertake to not 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 biological specimen it may be necessary to re-contact study participants, e.g. to obtain additional data or acquire additional biological specimen. To avoid overstretching the willingness of study participants to participate in DZHK studies, such secondary use projects are checked carefully, especially with regard to the significance for the expected research results and the time and effort involved for study participants. The identification of study participants to be contacted shall be handled by an Independent Trusted Third-Party Office. Details are regulated in Section 23.

(3) No commercial exploitation of the data and biological specimen transferred or provided by patients (see Section 4) as part of a secondary use project, or information obtained from the secondary use project, is permitted with the exception of clinical operation/health care. This principle does not apply to DZHK studies that may have a cooperation with industry. Individual cases are governed by the utilisation policy.

Section 7. Usage only within the framework of usage application and their approval

(1) Transferred data and biological specimen shall be used exclusively for the requested and approved purpose and only within the time frame for which the usage application was made and approved. Biological specimen shall also be used only in the laboratory specified in the MTA. Any terms and conditions contained in the approval must be observed. Any additional use of data or biological specimen – 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 biological specimen to a third party beyond the stipulations of the MTA is prohibited. If the use of data or biological specimen 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 biological specimen is prohibited.

Section 8. No claim to additional funding

The granting of access to or transfer of data and/or biological specimen 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, Responsible Scientists 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 biological specimen per the DZHK Publication Policy. One copy of the printed version (alternatively: digital version) must be submitted to the main office.

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

Section 10. Re-transfer and administration of secondary use project results

(1) Once the analysis has been completed and the data prepared the Responsible Scientists 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 runtime of MTA.

(2) In doing so, care must be taken to provide a sufficient, self-explanatory documentation of the data and 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 Transfer Office of the Clinical Research Platform. For delivery of the results to other scientists, a protection period of two years after end of the data and biological specimen MTA 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. Contractual Partners, from whose usage application the results originate, shall be informed about the transfer. Contractual Partners who applied for and received the right to utilise the results will be informed about the participation of Contractual Partners whose application was the originator of the results, to proceed in accordance with the Good Scientific and Good Epidemiological Practice³. This is regulated in detail in Section 11.

(4) The duty to store the data provided by the DZHK and the results re-transferred 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 re-transferred results and data are available later for inspection and subsequent analyses (see recommendation 6.1 of the Guidelines for Good Epidemiological Practice³).

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

Section 11. Right to publish and right to non-commercial use of the results of secondary use projects

(1) For any publication that use data, biological specimen, or results, the rules of Good Scientific Practice³ and the DZHK Publication Policy shall apply.
(2) Written publications that are partially or wholly based on data or biological specimen, 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 biological specimen must be named in an appropriate manner. Details are regulated in the DZHK Publication Policy.

(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 after 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 study participants to be traced.

Section 12. Deletion of data and return of unused biological specimen

(1) The Contractual Partner shall delete all transferred data no later than 5 years after the end of the MTA, 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 biological specimen not used by Contractual Partners for the intended purposes, for example when a secondary use project is not carried out, must be made available to the DZHK without delay, as a rule at the expense of the responsible scientists, provided that it is ensured that the quality remains unchanged. This is to take place in coordination with the Transfer Office, the UAC, and the relevant parties and in such a way that permits the further use of the remaining biological specimen. Should that not be possible, then, in coordination with the Transfer Office and the Contractual Partners, the unused biological specimen must be destroyed, insofar as the consent of the study participant is concerned. The Transfer Office must be informed in writing about the return / destruction of the unused material by email (use.access@dzhk.de).

Section 13. Liability of the DZHK

The liability of the DZHK is regulated in the individual MTA.

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

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

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 biological specimen. For all questions regarding the application procedure, please contact the DZHK main office (use.access@dzhk.de).

(2) Within the meaning of broad public benefit, access to data and biological specimen 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) Usage 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 biological specimen is regulated by a MTA (see Section 6 (3) as well as the DZHK utilisation policy as amended).

Section 16. Form and content of the usage application and notification

(1) The usage of data and biological specimen requires prior authorisation by the DZHK. Usage applications and notifications must be submitted to the UAC via the Transfer Office. This should be done using the form in Annex 1 or 2, which requests all information relevant for the authorisation in accordance with (2), shall be used after the relevant data and/or biological specimen collective has been prepared with the aid of the data catalogue and the Feasibility Explorer.

(2) The usage application must include the following information concerning:
   I. Applicant(s) (applicant(s), co-applicant(s), Contractual Partner(s), other participants e.g. cooperation partner(s)),
   II. Project information (project title, information on project finances, proposed project period, project description, scientific background, project objective, justification of feasibility, project design, relevance of the material and human resources available for carrying out the project, transfer to non-safe third countries without an adequacy decision),
   III. The Collective (use of the Feasibility Explorer),
   IV. biological specimen (type and quantities, reason for the biological specimen quantities required), parameters of the method of analysis to be used, requirements for biological specimen),
   V. Further information (publications, information regarding the need to re-contact study participants and, where applicable, the positive evaluation of the responsible ethics commission (see Section 3 (3)), further comments).

(3) The usage notification and approval shall contain the same specifications as in (2) with the exception of item III: Use of Feasibility Explorers. The DZHK study to which the usage notification refers should be indicated here.

Section 17. Examination of application, positive quality control of the secondary use project

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

(2) The UAC examines usage applications according to the following criteria:
(a) Identity and scientific reputation of the applicants (Responsible Scientists).
(b) The scientific justification for the secondary use 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 biological specimen.
(f) The application is consistent regarding the requested data/biological specimen 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/biological specimen 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 study participants 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 study participants 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 study participants complies with the requested usage.
(m) The financing concept for implementing the proposed secondary use project is plausible.

(3) If an application to utilise biological specimen is filed, the following additional criteria are taken into consideration to ensure optimal utilisation of the limited number of biological specimens:
   (a) The scientific justification for the use of the requested biological specimen, 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 biological specimen to be released to the scientific significance of the objective of the use of the biological specimen and to the total amount.
   (c) Obligation of the applicant to use the biological specimen economically and efficiently.
   (d) Consideration of existing similar biomarker determinations.
   (e) Minimisation of the number of thawing and freezing cycles to which biological specimen are subjected.

(4) Further experts may be consulted, e.g. representatives of the decentralized biobank, who are bound to secrecy by a confidentiality agreement. Applicants have the right to be heard.

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

(c) The usage 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 for secondary use projects working on the same or very similar questions and that the methods be jointly harmonised. Another possible condition is that the biological specimen be used only at a later point in time if this would mean a more efficient use of the biological specimen can be achieved.

(7) All Applicants, the Board of Directors of the DZHK and the respective Study Leaders 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 usage 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 biological specimen 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 usage 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 applicants will be asked to rewrite the application accordingly and to present it anew.

(10) If an usage 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 biological specimen with their respective current status (approved/completed/results published) are to be published on the DZHK Study Participant Information Platform5.

Section 18. Denial of utilisation approval

(1) Irrespective of the basic approvability of the secondary use project, the granting of the usage permit may be refused if the responsible scientists or other contributors have culpably and to a not inconsiderable extent violated these utilization regulations in a previous case.

(2) A significant violation exists, in particular, if:

(a) Access rights according to Section 4 were disregarded

5 Study Participant Information Platform (PIP) https://pip.dzhk.de/
(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 biological specimen was not returned or destroyed (Section 12) or
(g) Unlawful re-identification of study participants.

Section 19. Material (and data) transfer agreement (MTA)

(1) The prerequisite for the transfer of data and/or biological specimen following approval of an usage application is the conclusion of an MTA. Contractual Partners agree in this contract to comply with the terms and conditions of usage. The MTA specifies, in particular:
   (a) Start and end of the contract.
   (b) The data and/or biological specimen to be made available for the secondary use 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 biological specimen.
   (e) The latest date for deleting the data that was provided.
   (f) Other conditions and stipulations.

(2) The draft MTA to be used is attached as Annex 3 to this Use and Access Policy.

Section 20. Usage Notification

(1) The UAC 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) An usage notification and its approval (Section 16 (1, 3)) is possible only in the cases mentioned in this Use and Access Policy (Section 4 (5)).

(3) After examining the usage notification, the UAC 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/biological specimen.
   (b) The data/biological specimen can be used only under certain conditions.
   (c) The use of the data/biological specimen should be prohibited.

(4) 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.
(5) If the utilisation of the data is not prohibited, the abstract and the current status of the secondary use project analogous to an approved data usage application will be published on the DZHK website.

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

IV. Transfer of data or biological specimen

Section 21. Transfer of data

(1) Once the MTA 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 Scientists while observing the Data Protection Concept.

(2) For each study participant for whom data are incorporated into the data set to be transferred, a further check is carried out by the Transfer Office and the Independent Trusted Third-Party Office to determine whether the existing declaration of consent permits the utilisation of this data.

(3) Personal identification data shall not be made accessible or, if necessary, shall be rendered unrecognisable by suitable measures prior to handover (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 Trusted Third-Party Office and will not be transferred to the corresponding Contractual Partners.

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

(5) 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 Independent Trusted Third-Party Office 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 all Responsible Scientists specified at data recipients by the MTA.

Section 22. Transfer of biological specimen

In addition to the regulations set out in Section 21 for the transfer of biological specimen, the following provisions shall apply:
(1) On the basis of the MTA, the Transfer Office will prepare a table that provides information on the selection of the study participants in anonymised form and the amount of the required biological specimen. The Transfer Office requests the decentralised biobank to hand over the biological specimen.

(2) The biological specimen will be transferred only to a recipient named by the Contractual Partners who, as a rule, is the Responsible Scientist. Recipients of biological specimen are named in the MTA. Biological specimens are handed over by the decentralised biobank to designated recipient of biological specimen as soon as possible, but no later than within two weeks. Project-specific pseudonyms are not transferred to the corresponding recipient of biological specimen or contract partners by the decentralised biobanks.

Section 23. Person-identifying information, contacting study participants

The identification of study participants (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 Trusted Third-Party Office. In the event of approval, the Independent Trusted Third-Party Office shall carry out the identification. Study participants may only be contacted by the participating DZHK PI or the DZHK scientist who is maintaining the contact with the Study participants. This contact may, however, be coupled with a request for the study participant to consent to the transfer of contact data to the Responsible Scientists and to consent to contact by the Responsible Scientists for the exclusive purpose of carrying out the approved secondary use project. In every case the procedure described above requires the informed consent of the concerned study participant according to Section 3 (1).

Section 24. Reimbursement of costs

(1) The decentralised biobanks, the Clinical Research Platform, or the DZHK e.V. may incur additional material and/or staffing costs in connection with the supply, preparation, storage and transfer of data/biological specimen. This may result in costs downstream. As a rule, such costs shall be borne by the Contractual Partners. Details are to be regulated in the MTA as needed.

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

V. Legal consequences in case of infringements

Section 25. Revocation or restriction of usage rights

(1) In the event of violations of these Terms of Use or of the provisions of the MTA or of conditions imposed on the use of data, the DZHK may withdraw the granted permission to use data from all contracting partners in whole or in part.

(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 event that a usage permit is revoked, the use of the data and/or biospecimens provided shall be discontinued immediately. The data shall be deleted immediately and unused biospecimens shall be returned to the respective decentralized biobank without delay. Results are to be forwarded to the transfer agent. Restrictions of the rights of use shall be agreed upon by means of an addendum to the MTA, which all contracting parties shall be obliged to conclude.

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

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

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 12 August 2014 and was updated to version 1.1 on 23 March 2021.

Section 27. Acknowledgements

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: Usage application form
Annex 2: Usage notification form
Annex 3: Material (and data) transfer agreement form (MTA)