

Use of Data and Biospecimen

Secondary Use Projects

**- NOTIFICATION FORM -**

|  |  |
| --- | --- |
| To: | Use and Access Committee of the DZHK |
| Via: | Use and Access Office of the DZHK e.V. |
|  |  |

|  |
| --- |
| Access to data and biospecimens is regulated by the [DZHK Use and Access Policy](https://dzhk.de/fileadmin/user_upload/DZHK-Nutzungsordnung_Version_1.1.pdf). |
| Please submit the signed application to: use.access@dzhk.de |
| **By submitting this application to the Use and Access Committee, the applicant(s) agree(s) to the Use and Access Policy regulations and pledge(s) to abide by them.** |

Applicant and further parties involved

|  |  |  |
| --- | --- | --- |
| **1.1** |

|  |
| --- |
| **Applicant** (has to be the principle investigator of the respective DZHK study) |

 |
|  | Surname, first name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Institute | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Street | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Post code | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| City | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Telephone number | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Email | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **1.2** | **Co-applicant and / or responsible scientist** |
|  | Surname, first name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Institute | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Street | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Post code | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| City | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Telephone number | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Email | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **1.3** | **Statistician / bioinformatician** |
|  | Surname, first name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Institute | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Street | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Post code | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| City | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Telephone number | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Email | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **1.4** | **Contractual Partner** (if different from 1.1) |
|  | Surname, first name | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Institute | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Street | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Post code | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| City | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Telephone number | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Email | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **1.5** | **Further parties involved** (e.g. employees, cooperation partners) (role in the project, surname, first name, institution, address) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

****project specification****

|  |  |  |
| --- | --- | --- |
| **2.1** | **Project title** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **2.2** | **Keywords** (maximum of 5) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **2.3** | **Objectives** |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **2.4** | **Time frame foreseen** for the project |
|  | Duration of the project / data utilisation in months | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Laboratory analysis - period in months | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **2.5** | **Project outline** |
| **a)** | Abstract (maximum of 500 words) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **b)** | Hypothesis (maximum of 100 words) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **c)** | Study design and methods (maximum of 500 words) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **d)** | Possible conclusions, relevance of results (maximum of 100 words) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

****Participant Subset****

Please define the subset of participants you want to analyse.

Note: If you need to split the subset into sub subsets according to some criteria, please make sure, this information is mentioned where necessary.

|  |  |  |
| --- | --- | --- |
| **3.1** | **Number of total cases**  | n = \_\_\_\_\_\_ (min. \_\_\_\_\_\_, max. \_\_\_\_\_\_ ) |
| **3.2** | **Justification of feasibility** / required number of cases (e.g. power analysis, dropout) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Calculated dropout | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3.3** | Please state the name and acronym of the respective **DZHK study**. |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3.4** | **Inclusion and exclusion criteria**Please specify all criteria participants should fulfil to be suitable for your analyses (e.g. 50-year-old males with diabetes and no heart failure). **Use** **the most current version of the data record table of your study to define the criteria. You can get the data record table from the DZHK Data Handling (**dzhk.support@med.uni-goettingen.de**).**Use visits (sheet 2 “Formularübersicht”), table identifiers (corresponding eCRF sheet) and database column names (column “K” of the corresponding eCRF sheet) to define the desired characteristics.Criteria are linked via conjunction (AND) by default. Please use brackets and an OR statement (disjunction) if you need the linkage otherwise. Important: If you need an item not to be null in the follow up visit, because you need this information for your project, this item is also an inclusion/exclusion criterion and needs to specified here! Currently, follow up visits are rarely complete, so it is not sufficient to simply request the follow up data. Example: * Baseline:
	+ mnpdzhk1basis: (70 <= basis\_gewicht <= 100 OR basis\_groesse >=175) AND basis\_geschlecht == „female“
	+ mnpdzhk1cardiomyo: kardiag\_dilatkard == “yes”
* Follow-Up: mnpdzhk1cardiomyo: kardiag\_dilatkard == “yes”
 |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Clinical data

|  |  |
| --- | --- |
| **4.1** | Please state the names of the **eCRFs modules** and the **visits** of the data you need for your project analysis according to your data record table (sheet 2 “Formularübersicht”). Example: * Baseline: Anamnesis and Clinical Diagnoses (incl. Basic Data Set), 6-Minute Walking Test
* Follow-Up: Anamnesis and Clinical Diagnoses (incl. Basic Data Set)
 |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Biospecimens

Please specify the desired study specific biospecimens per participant if you are applying for, otherwise leave blank.

|  |  |
| --- | --- |
| **5.1** | **Type and quantity of requested biospecimen** |
|  | Specimen type | Quantity and Unit | Justification of quantity | Visit(s) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_ |
|  | In case biospecimens of multiple visits are applied for, is the lack of biospecimen of one visit an exclusion criterion of the specific participant (or is it “just nice to have”)?  |  |
| **5.2** | **Per type: Exact description of each parameter that is to be determined using the biospecimens, including the intended preparation, pre-analytics and special analysis** |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Are genetic studies planned? |  |
| In case of genetic studies, are genome-wide studies planned (e.g. whole genome sequencing)? |  |
| **5.3** | **Laboratory resources for biospecimens analysis / proof of technical conditions**(Personnel, know-how, equipment / devices, storage of biospecimens) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **5.4** | **Specific requirements for biospecimens**(e.g. "must not have been previously thawed") |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

imaging data

Please specify your desired study specific imaging data if you are applying for, otherwise leave blank.

|  |  |
| --- | --- |
| **6.1** | **Modality and visits of requested imaging data** |
|  | Modality | Visits |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| In case imaging data of multiple visits is applied for, is the lack of imaging data of one visit an exclusion criterion of the specific participant (or is it “just nice to have”)?  |  |
| **6.2** | **Per modality: Exact description of the planned analysis using the imaging data** |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **6.3** | **Proof of resources for imaging data analysis** (Personnel, know-how, software) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

****Additional Project information****

|  |  |
| --- | --- |
| **7.1** | Is it necessary to **re-identify** the included participants in order to collect an appropriate amount of additional clinical data, biospecimens or imaging data? (See section 23 of the DZHK Use and Access Policy)  |
|  | Re-identification necessary?  |  |
| In case a re-identification is necessary, please explain why and what you are going to collect. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **7.2** | Do you want to **compare** the provided data **to other databases** on participant level? |
|  | Other databases necessary?  |  |
| In case other databases shall be included, please give an explanation and name the database(s).  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **7.3** | Does the use of the requested data / biospecimens involve the **transfer to a non-EU country without an adequacy decision**? |
|  | Transfer necessary? |  |
| In case a transfer is necessary, please give an explanation. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

****FURTHER INFORMATION / DETAILS****

|  |  |
| --- | --- |
| **8.1** | **Financing** If you are applying for biospecimens, make sure you can also finance biospecimen shipment from an unknown number of centres, analyses etc.. |
|  | Please indicate your financial sources. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **8.2** | **Ethics vote**Please note that if the application is recommended, a **positive ethics vote** by the medical ethics committee in charge for your institution must be submitted before data / biospecimens can be released. The ethics vote meant here relates to the planned project and not to the underlying data collection. Please check if the ethics vote for your study contains the planned project idea or if you need an additional vote. |
|  | Positive ethics vote existing? |  |
| In case a positive ethics vote does not yet exist, is it already submitted? |  |
| **8.3** | **Further remarks / comments on the part of the applicant** (maximum of 50 words) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Final statement

|  |
| --- |
| **Title of the project** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Name of statistician / bioinformatician** |
| From the bioinformatics side, the present application was checked with regard to power calculation, design and methods and confirmed by signature. |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
| **Place, date** | **Signature of statistician/bioinformatician** |
| **Name of applicant / coordinating investigator** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
| **Place, date** | **Signature of applicant** |

The following information on protection and processing of personal data explains which data we may collect and what happens to any personal data. The information applies to the submission of applications for funding of projects by the DZHK e. V.

**Information to be provided pursuant to Article 13 GDPR**

We are obliged to inform you how your personal data are collected and processed:

**Controller**

The controller responsible for collection and processing of the data is:
Deutsches Zentrum für Herz-Kreislauf-Forschung e. V. (DZHK)
Potsdamer Str. 58
10785 Berlin

**Purpose of the processing**

We process your data to process proposals you submitted for the conduct and financing of a research project. Legal basis of this processing activity is Article 6 (1) point (b) GDPR.

**Categories of personal data processed**

The following personal data are processed:

Your name and first name and contact details, including postal address, telephone and fax numbers, email address and if necessary further contact details, professional qualification and career, curriculum vitae.

**Categories of recipients**

Internally, employees of the administrative office of the Deutsches Zentrum für Herz-Kreislauf-Forschung e. V. have access to the personal data. In the course of processing your proposal, the proposal including your personal data is transferred to members of the DZHK committees and external reviewers.

**Transfer of personal data to a third country**

The personal data you provided may be transferred to recipients in third countries for the purpose of evaluation. In the case of transfer, suitable safeguards are provided to ensure an adequate level of protection within the meaning of Article 46 GDPR.

**Erasure of personal data**

The personal data are deleted after the end of processing when their storage is no longer necessary unless law requires storage of the personal data. In individual cases a storage of individual data for a longer period of time may be required. The period of storage in these cases depends on legal obligations concerning storage of data, for example the Fiscal Code of Germany (six years) or the Commercial Code (ten years).

**Data protection officer**

If you would like to receive further information about data protection, please contact our data protection officer.

Lawyer Marcel Wetzel
Theodor-Heuss-Platz 4
14052 Berlin
Email: mail(at)wetzel.berlin
Telephone: +49 30 895 66 160
Fax: +49 30 895 66 161

**Provision of personal data or no provision of personal data**

The provision of personal data is required in order to process the proposal you have submitted. Proposals cannot be processed when personal data are not provided.

**Automated decision-making**

There is no automated decision-making and profiling.

**Your rights**

As a data subject, you have the right of access to the personal data concerning you (Article 15 GDPR) and to obtain the rectification of inaccurate personal data concerning you (Article 16 GDPR) or to obtain erasure of personal data concerning you where one of the grounds of Article 17 GDPR applies, for example when the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed. You have also the right to obtain restriction of processing where one of the conditions referred to in Article 18 GDPR applies and in cases pursuant to Article 20 GDPR the right to data portability. You have the right to object, on grounds relating to your particular situation, to processing of personal data concerning you which is based on Article 6 (1) point (e) or (f). In such a case we ask you to provide the grounds. Every data subject has the right to lodge a complaint with a supervisory authority, if the data subject considers that the processing of personal data relating to her or him infringes the provisions of data protection (Article 77 GDPR).