

Use of Data and Biospecimen of the DZHK Heart Bank

Secondary Use Projects

PART II – RESOURCE SPECIFICATIONS

**- SUBFORM A: Resource with Liquid Biospecimens and Image Data -**

This resource contains different liquid specimens (DZHK Basis Biobanking), imaging data of the heart and at least a minimal clinical data set (DZHK Basic Data Set) originally collected in DZHK studies. For more information see [Resource with Liquid Samples and Image Data](https://dzhk.de/en/dzhk-heart-bank/data-and-biospecimens/resource-with-liquid-samples-and-image-data/) or contact us directly via use.access@dzhk.de.

****Assignment to the project****

Please indicate applicant name and project title for correct allocation to the project (according to application form part I).

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| **Applicant name** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Project title** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

****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.

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| **1.1** | **Number of total cases**  | n = \_\_\_\_\_\_ (min. \_\_\_\_\_\_, max. \_\_\_\_\_\_ ) |
| **1.2** | **Justification of feasibility** / required number of cases (e.g. power analysis, dropout) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Calculated dropout | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **1.3** | **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 [DZHK Data Catalogue](https://dzhk.de/en/research/data-and-sample-collections/data-catalogue/) to get an overview of what is applicable or use the [Feasibility Explorer](https://esb.mi.med.uni-goettingen.de/dzhk/feasibilityexplorer/) for a rudimentary overview.  |
|  | Use the provided table [InclusionExclusionCriteria](https://dzhk.de/en/dzhk-heart-bank/submitting-applications/) to define all inclusion and exclusion criteria. Please make sure to follow the instructions on the first sheet.  |
| The completely filled in table is attached. |  |  |
|  |

****Clinical data****

By default, you will receive a minimal data set ([DZHK Basic Data Set](https://dzhk.de/en/research/data-and-sample-collections/data-catalogue/anamnesis-and-clinical-diagnoses-incl-basic-data-set/)) for your participant subset and the items you specified in 1.3.

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| **2.1** | If you need additional data for your project analysis, please use the table [ItemsProjectAnalysis](https://dzhk.de/en/dzhk-heart-bank/submitting-applications/) to specify (e.g. all items of the echocardiography form and a couple of items of the laboratory form). Please make sure to follow the instructions on the first sheet.For more information on the available data, have a look at the [DZHK Data Catalogue](https://dzhk.de/en/research/data-and-sample-collections/data-catalogue/).  |
| Are more items needed? |  | 🡪 The completely filled in table is attached. |
|  |
| **2.2** | Which visits are of interest to you? | [ ]  | Baseline |
| [ ]  | Follow Ups |

biospecimens

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

|  |  |
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| **3.1** | **Type and quantity of requested biospecimen** |
|  |  | Type | Quantity | Justification of quantity |
| [ ]  | EDTA-plasma | \_\_\_\_\_\_\_\_ µl | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  | Citrated plasma | \_\_\_\_\_\_\_\_ µl | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  | Serum | \_\_\_\_\_\_\_\_ µl | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  | Buffy Coat | \_\_\_\_\_\_\_\_ µl | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  | Urine | \_\_\_\_\_\_\_\_ µl | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3.2** | **Per type: Exact description of each parameter that is to be determined using the biospecimens, including the intended preparation, pre-analytics and special analysis** |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_0\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Are genetic studies planned? |  |
| In case of genetic studies, are genome-wide studies planned (e.g. whole genome sequencing)? |  |
| **3.3** | **Laboratory resources for biospecimens analysis / proof of technical conditions**(Personnel, know-how, equipment / devices, storage of biospecimens) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_0\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **3.4** | **Specific requirements for biospecimens** (e.g. "must not have been previously thawed") |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_0\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

****Imaging data****

Please specify the desired imaging data if you are applying for, otherwise leave blank.

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| **4.1** | **Modality and visits of requested imaging data of the heart** |
|  |  | Modality | Visits |
| [ ]  | CT (Computed Tomography) | [ ]  | Baseline | [ ]  | Follow Ups |
| [ ]  | ECG (Electrocardiography (10sec 12-lead ECG)) | [ ]  | Baseline | [ ]  | Follow Ups |
| [ ]  | MR (Magnetic Resonance) | [ ]  | Baseline | [ ]  | Follow Ups |
| [ ]  | US (Ultrasound (Echocardiography)) | [ ]  | Baseline | [ ]  | Follow Ups |
| [ ]  | XA (X-Ray Angiography) | [ ]  | Baseline | [ ]  | Follow Ups |
| 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”)?  |  |
| **4.2** | **Per modality: Exact description of the planned analysis using the imaging data** |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_0\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **4.3** | **Proof of resources for imaging data analysis** (Personnel, know-how, software) |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_0\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

****Additional Project information****

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| **5.1** | 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. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **5.2** | Do you want to **link** 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). | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **5.3** | 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. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |