DZHK
Deutsches Zentrum für
Herz-Kreislauf-Forschung

DZHK-SOP-B-03

Collection of Biosamples

(Study centres without DZHK Clinical Study Unit)

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Note: Printouts are not subject to the update process!

Change note: Changes to wording
Editorial changes

	Scientific author	Scientific review	Approval WGCR spokesperson	Approval DZHK
Name	Tanja Zeller	Ivonne Wallrabenstein	Monika Kraus	Katharina Eulenburg
Date				
Signature	**This SOP is a translation from the original German SOP and valid without signatures.**			

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1 Introduction

1.1 List of abbreviations

Abbreviation	Full form
BD	Becton Dickinson AG
DZHK	German Centre for Cardiovascular Research
EDTA	Ethylene-diamine-tetra-acetic acid
eCRF	Electronic case report form
IKCL	Institute for clinical chemistry and laboratory medicine
SOP	Standard operating procedure

1.2 Objectives

This standard operating procedure is used within the DZHK projects (usually a clinical study, registry or cohort) to describe the process of collecting liquid samples up to transportation to the laboratory (for further processing) under standardized conditions.

Core elements are highlighted in grey in this SOP.

1.3 Background

In scientific studies, various approaches are used to examine human biosamples, such as the determination of (circulating) biomarkers, determination of standard laboratory values, OMICs procedures, DNA/RNA extraction or "biomonitoring", for which a high sample quality is the basis. In order to minimize pre-analytical factors, which have a significant influence on sample quality, the steps of collection, processing and storage must be standardized according to DZHK SOPs. This standardization not only ensures that as many of the above-mentioned techniques as possible can still be carried out after long-term storage of the biosamples, but also enables the comparability of the analytical data obtained from the biosamples processed and stored at the different study centres at a later stage.

1.4 Terms and definitions

Biopsamples *are e.g. blood, urine, stool and tissue as well as the materials obtained after processing (e.g. plasma, serum, extracted DNA, RNA, stem cells).*

DZHK-biobanking[1] for the DZHK Heart Bank

The DZHK Heart Bank combines valuable resources of biosamples, associated clinical data, image data and genomic data, which are collected within the framework of DZHK projects and other projects. The aim is to make a sustainable contribution to research and the improvement of health. The open resource is available for research projects worldwide. DZHK biobanking is carried out with a firmly defined ***DZHK-set[2]***. The DZHK Heart Bank contains all the DZHK sets gained.

[1] Former „DZHK-Basic-Biobanking“

[2] Former „DZHK-Basic-Set “

Study biobanking[3] to answer the research question

In addition to the DZHK set, a study-specific sample collection according to this SOP may be necessary. The composition of these ***study-sets[4]*** as well as the determination of the collection times is up to the responsible Principle Investigator of the respective DZHK project and will be communicated to the participating study centres and scheduled at the initiation event at the latest.

SecuTrial®: In addition to the documentation of clinical items, the clinical data management system is also used to record a defined biosample data set (via eCRF). After the data collection is completed, the correctness, completeness and plausibility are confirmed by assigning a Review A (see DZHK-SOP-P-01 Data Review) and the biospecimen data of the eCRF is released for transfer to the central laboratory information and management system of the DZHK (DZHK-LIMS).

2 DZHK-set

A standardized DZHK-set is taken from each participant of a DZHK project **once at the baseline visit (before intervention)**, provided that the participant has consented. The composition of the DZHK set is listed below in Table 1. According to the established clinical routines, either BD or Sarstedt tubes can be used.

Table 1 Type, volume and number of primary vessels

	Primary vessel	BD		Sarstedt	
		volume	number	volume	number
DZHK-set	serum	10,0 ml	1	7,5 ml	1
	EDTA	10,0 ml	1	7,5 ml	1
	citrate	2,7 ml	1	3,0 ml	1
	urine	11,0 ml	1	10,0 ml	1

3 Requirements for biosample collection and documentation

The DZHK kits and any study kits are prepared and provided centrally by the Institute of Clinical Chemistry and Laboratory Medicine (IKCL) at Greifswald University Medical Centre (laborstudien@med.uni-greifswald.de). The sample sets are ordered by a person authorized at the centre using a request form (in German).

The sample sets contain:

- Labelled primary vessels with identification codes
- Labelled aliquot tubes placed on a rack
- Label with identification code for the urine beaker
- Additional labels with identification code without material identification
- Biosample label with identification code of the sample set

Also required are:

[3] Former „Study specific biobanking“

[4] Former „Study-specific set “

- User access to SecuTrial® and activated module for sample documentation
- LIMSPSN (pseudonym for biosample documentation, which can be viewed and printed out via SecuTrial® during registration of patients. The pseudonym consists of a constant prefix and nine digits that vary for each participant, e.g. lims_123456789)
- Blood collection kit
- Instructions for sterile urine collection for participants (see information sheet "Collection of midstream urine" in the appendix of this SOP)

4 Procedure for biosample collection and documentation

1.5 Specifications

Biosample collection must be performed by trained staff in accordance with the locally applicable requirements of this SOP. Deviations from the following requirements do not lead to the exclusion of participants from the study, but are documented as deviations on the biospecimen collection form and in SecuTrial® (see section 6.4).

The following must also be noted:

- Compliance with current hygiene regulations
- Suitable disposal options for cannulas, swabs, etc.

1.6 Flow Chart

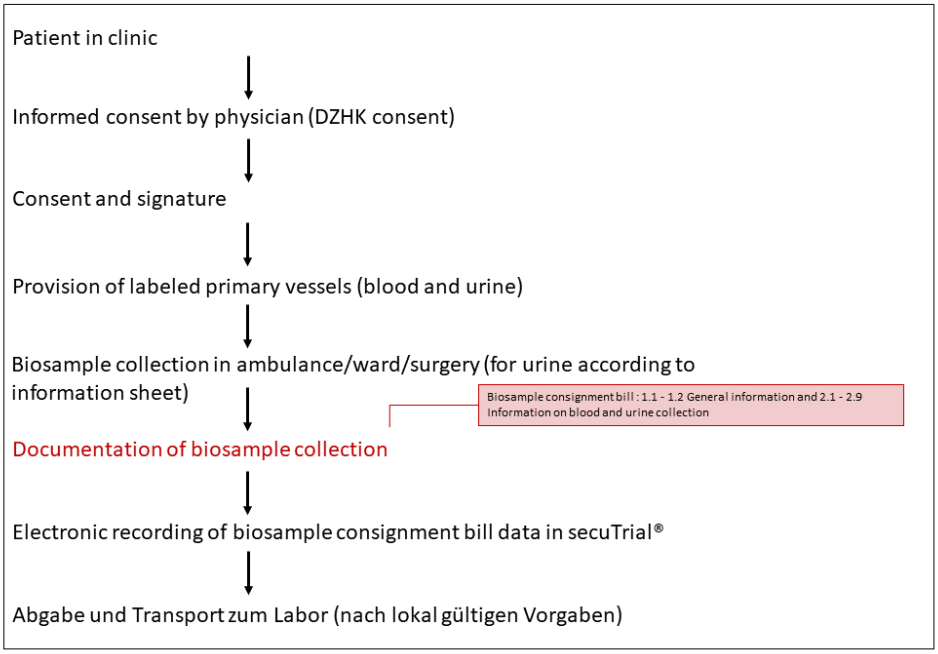

Fig.1: Overview of collection and documentation of biosamples.

1.7 Biosample collection procedure and documentation in detail

Blood collection:

- Provision of the primary vessels with identification codes

- Resting time in unchanged body position before blood collection: 5 minutes
- Stagnation time < 1 minute
- Collection site: Vena cubitalis
- Sample sequence for blood collection: serum, citrate, EDTA
- Release of congestion after blood collection has started, i.e. when blood flow into the primary vessel is visible
- No repeated fist closure
- Immediate swivelling already when changing the primary vessels
- Upright positioning of the primary vessels in the primary vessel/tube rack

Urine collection:

- Labelling of the urine beaker
- Information for participants by means of the information sheet "Collection of midstream urine" in the appendix of the SOP
- Collection of midstream urine

Documentation:

- All information on biosample collection on the biosample consignment bill
- Deviations from the SOP on the biosample consignment bill
- Transfer of the documentation to SecuTrial®

Sample transportation:

- The transportation of the primary vessels with the biosample consignment bill to the laboratory for further sample processing should take place **within 60 minutes** of biosample collection if possible.

1.8 In case of deviation

Any deviations from the specifications described in sections 6.1-6.3 must be documented on the biosample consignment bill and in SecuTrial® under "3. Special features". At least the following circumstances must be recorded as deviations:

Blood collection and transportation:

- Stagnation time longer than 1 minute
- Sample sequence (serum, citrate, EDTA) not adhered to during blood collection
- Repeated fist closure
- No immediate swirling when changing primary vessels
- No upright storage of the primary vessels in the primary vessel/tube rack
- The transportation of the primary vessels to the laboratory for further sample processing took longer than 60 minutes after the biosample collection
- One of the blood samples could not be collected

Urine collection:

- No urine was collected/released

5 Literature

Guideline of the German Medical Association for the quality assurance of laboratory medical examinations (in German)**.** Deutsches Ärzteblatt | DOI: 10.3238 / arztebl.2019.rili_baek_QS_Labor20192312

6 References to existing DZHK-SOPs

The latest available version is valid.

SOP-ID	**Titel**
DZHK-SOP-P-06	Acquisition-IDAT-Informed Consent
DZHK-SOP-B-04	Biosample processing (without DZHK Clinical Study Units)

7 Changes

Changes compared to former version.

Section	Description of the change compared to the previous version.
Whole document	Wording former biomaterial becomes biosamples former DZHK basic biobanking becomes DZHK-biobanking former DZHK Basic set becomes DZHK-set former study specific biobanking becomes study biobanking former study specific sample set becomes study-set
Whole document	Editorial changes

8 Participating persons

Name	**Role**	**Contribution**
Prof. Dr. Tanja Zeller	First author	Draft
Dr. Ivonne Wallrabenstein	Reviewer	Scientific review
Dr. Ilka Wilhelmi	DZHK main office	Coordination

9 Appendix

9.1 Info sheet urine collection

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Dear participant,

You have consented to participate in a Germany-wide study, a registry or a cohort of the German Center for Cardiovascular Research (DZHK). Your consent includes the collection and processing of urine.
Your urine will be collected to measure various components that can provide information about the function of your kidneys or indicate the presence of diseases.

Please follow these instructions for collecting urine:

1. Please ensure that the urine cup is labelled or marked with your identification code (sticker).
2. Open the urine cup marked with the label without touching the inside of the container or the lid!
3. Only hold the open urine cup in the flow of urine once you have started urinating.
4. If possible, fill the urine cup halfway. Discharge the remaining uncollected urine into the toilet.
5. Close the urine cup without touching the inside of the cup or lid. If necessary, dry the outside of the cup with a paper towel (and disinfectant).
6. Wash your hands.
7. Dispose the closed urine cup according to the instructions given on site.

Thank you!