DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

July 2020

DZHK Item Catalogue

The DZHK aims to standardise data collection amongst its clinical studies in order to enable secondary use of the data across studies. Therefore, Standard Operating Procedures (SOPs) as well as acquisition modules for common cardiological assessment procedures are available. This Item Catalogue provides an overview of the existing DZHK-wide standardised acquisition modules. The attached secuTrial® forms contain each module's items with their respective expressions and intend to serve as a guide to study leaders and coordinators for the preparation of the eCRF. The basic data set contains 42 items, which are mandatory to be collected in every DZHK study. Other modules can be chosen depending on the study protocol. In order to maintain cross-study comparability, we recommend using as many of the harmonised items as possible. In addition, the modules can be extended by study-specific items.

Contents

Harmonised modules with corresponding SOPs

For the following harmonised modules there are SOPs that describe how to perform the examinations. The corresponding SOP for each module can be found on the DZHK website.

Anamnesis and Clinical Diagnosis (incl. Basic Data Set) (DZHK-SOP-K-02)

The module Anamnesis and Clinical Diagnosis (incl. Basic Data Set) is used to accurately record known cardiovascular risk factors, previous diagnoses and interventions. The collected findings enable a detailed assessment of a patient's cardiovascular risk.

The module contains among others the mandatory basic data set with 42 items. In the following, these items are labeled with ** (double asterisk).

The examinations ought to be performed according to DZHK-SOP-K-02.

DZHK-SOP-K-02:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020

Anamnesis and Clinical Diagnoses (incl. Basic Data Set**) (13.07.2020 - 10:34:54 (MESZ))

General information relating to the anamnesis

I. Date of examination** ☐ tt.mm.jjjj
○ unknown ○ not assessed

II. Quality level* ☐ 1)

Hilfe:
Level 1
The examination is performed in accordance with the guidelines of the medical associations.

Level 2
The examination is performed in accordance with the specifications of the DZHK SOP. Minimum requirements to ensure the quality of the implementation and the examiners are defined in the SOP.

Level 3
The examination is performed in accordance with the specifications of the DZHK SOP and certification of the examiners: Definition of intra-observer and inter-observer variability (standard of epidemiological studies).

1. Physical Examination and Socio-demographic Data

1.1. Sex** ○ male ○ female ○ diverse ○ unknown ○ not assessed

1.2. Date of Birth** ☐ mm.jjjj

1.3. Height** ☐ cm
○ unknown ○ not assessed
○ estimated ○ measured

Hilfe: Height is measured in the standing position, without shoes and without head covering. Preferentially, measured data should be collected; only when this is not possible (e.g. in the case of bed- ridden patients) should one estimate the values or resort to information provided by the proband

1.4. Weight** ☐ kg
○ unknown ○ not assessed
○ estimated ○ measured

Hilfe: Weight is measured in normal street clothing, without a jacket and without shoes. Preferentially, measured data should be collected; only when this is not possible (e.g. in the case of bed- ridden patients) should one estimate the values or resort to information provided by the proband

1.5. Ethnicity: Caucasian** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: A person's ethnic origin is defined by their ancestry in relation to a specific ethnic group. This can be determined biologically and/or geographically on the basis of membership of a certain settlement group. Accordingly, a person's skin colour can also be broadly defined. The colour spectrum can be differentiated from light to dark skin colour

1.6. Black skin colour?** ○ yes ○ no ○ unknown ○ not assessed

1.7. Family history of myocardial infarction or stroke in parents, siblings or children under the age of 65 for women or under 55 for men** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a medically diagnosed myocardial infarction or stroke in one or both biological parents, biological siblings (including half-siblings) or biological children, provided the female relative was under age 65, or the male relative under age 55 (when the myocardial infarction/stroke occurred)

2. Cardiovascular risk factors

2.1. Diabetes mellitus** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as diabetes which has been diagnosed and/or treated by a doctor.
The American Diabetes Association criteria are:
haemoglobin A1c ≥ 6.5 % or a fasting blood glucose level of ≥ 126 mg/dl or a 2-hour blood glucose level of ≥ 200 mg/dl in the oral glucose tolerance test

2.2. Arterial hypertension** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis of arterial hypertension which was diagnosed and/or is being treated by a doctor. Treatment can consist of e.g. dietary changes, physical activity and/or medication. Systolic blood pressure values ≥ 140 mmHg and/or diastolic blood pressure values ≥ 90mmHg measured by a doctor on at least two separate days after a 5- minute resting phase qualify for a diagnosis of arterial hypertension

2.3. Dyslipidaemia** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis of dyslipidaemia which was diagnosed and/or is being treated by a doctor.
One or more of the following criteria:
total cholesterol ≥ 200 mg/dl,
LDL cholesterol ≥ 130 mg/dl,
HDL cholesterol < 40 mg/dl (men) and < 50 mg/dl (women)

2.4. Smoker** ○ yes ○ no ○ ex-smoker (stopped ≥ 6 mth. ago) ○ unknown ○ not assessed

Ex-smoker since** ☐ jjjj
○ unknown ○ not assessed

Pack years* ☐
○ unknown ○ not assessed

Hilfe: Is defined as current or previous use of cigarettes, cigars, pipes or smokeless tobacco. “Yes” for daily or occasional smoking (≥ 1x/month);
“Ex-smoker“ for abstinence of more than 6 months; ex-smoker since …; “No“ for “never smoked“.
Pack years is the product of the number of years of cigarette smoking multiplied by the average number of packs smoked per day. Example: A patient who has smoked 2 packets of cigarettes per day for 20 years has 40 pack years

2.5. Drinks per week* ☐
○ unknown ○ not assessed

Hilfe: Drinks per week is the number of alcoholic drinks consumed per week. One drink is defined as e.g. 0.25 l of beer, 0.1 l of wine or 0.02 l of spirits. Example: A patient who drinks 0.5 l beer on average two times every week has 4 drinks per week

2.6. Medically diagnosed alcoholism** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis of alcoholism which was diagnosed and/or is being treated by a doctor

2.7. Renal failure* ○ yes ○ no ○ unknown ○ not assessed

2.7.1. Degree of renal dysfunction*
○ 1 – eGFR 90 ml/min or higher
○ 2 – eGFR 60–89 ml/min
○ 3 – eGFR 30-59 ml/min
○ 4 – eGFR 15-29 ml/min
○ 5 – eGFR < 15 ml/min or current dialysis dependency
○ unknown
○ not assessed

Hilfe: This includes all patients who exhibit reduced renal function. If known, the degree of renal dysfunction should be quantified by the estimated Glomerular Filtration Rate (eGFR)

2.8. Current Dialysis Dependency** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as current regular, at least weekly, renal replacement therapy (including haemodialysis and peritoneal dialysis) within the last 30 days

3. Cardiac Diagnoses (Anamnesis and Previous Findings)

3.1. Coronary heart disease** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Coronary heart disease is defined as a current or previous diagnosis by a doctor with one or more of the following criteria:
- coronary artery stenosis of ≥ 50 % (diagnosed by cardiac catheterization or another direct coronary artery imaging method),
- prior coronary artery bypass operation,
- prior percutaneous coronary intervention,
- arteriosclerosis-induced myocardial infarction

3.2. Status post myocardial infarction** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Acute myocardial infarction is defined as demonstrated evidence of myocardial necrosis in a clinical setting which is consistent with myocardial infarction. One or more of the following criteria must apply:
- Evidence of an increase or decrease of a cardiac biomarker (preferably troponin) with at least one value above the 99 % percentile of the upper reference limit and, additionally, at least one of the following factors:
- symptoms of ischaemia, angina pectoris,
-ECG changes indicative of new ischaemia, e.g. ST segment elevations or a new left bundle branch block, development of pathological Q waves in the ECG,
- imaging studies show a loss of viable myocardial tissue or new regional wall motion abnormalities,
- angiographic evidence of stenosis/blood vessel blockage

3.3. Cardiomyopathy**
If the response to this question is "yes", please complete the "Cardiomyopathy Diagnostics" form.
○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a diagnosis by a doctor of a primary heart muscle disease.

3.4. Heart failure**
○ yes ○ no ○ unknown ○ not assessed

3.4.1. S.p. decompensation*
○ yes ○ no ○ unknown ○ not assessed

3.4.2. Initial diagnosis of heart failure*
☐ jjjj
○ unknown ○ not assessed

3.4.3. Current NYHA class*
○ I ○ II ○ III ○ IV ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis and documentation by a doctor of heart failure, based on the following symptoms: shortness of breath with mild exertion, recurrent shortness of breath when sitting, fluid overload or pulmonary rales, distention of the neck veins, pulmonary oedema on physical examination or pulmonary oedema on chest x-rays. Documentation of reduced left ventricular function alone in the absence of clinical signs of heart failure does not meet the criteria for heart failure.

NYHA class: Classification of the patient's symptoms based on the New York Heart Association classification of heart failure:
- NYHA I: No symptoms
- NYHA II: Symptoms with heavy physical exertion
- NYHA III: Symptoms with light physical exertion
- NYHA IV: Symptoms while at rest

3.5. Atrial fibrillation/flutter**
○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as a current or previous diagnosis by a doctor of atrial fibrillation or atrial flutter. It is defined as an episode of atrial fibrillation or atrial flutter lasting at least 30 seconds or atrial fibrillation with evidence on the surface ECG or during pacemaker interrogation

3.6. Current or previous diagnosis by a doctor of heart valve disease**
○ yes ○ no ○ unknown ○ not assessed

Hilfe: Is defined as heart valve disease (incompetence or stenosis), which has been diagnosed and/or treated by a doctor

3.7. Diagnosis by a doctor of endocarditis*
○ yes ○ no ○ unknown ○ not assessed

Hilfe: If at any time, currently or in their previous medical history, a patient has been diagnosed by a doctor with endocarditis (heart valve inflammation), it will be documented here

3.8. Diagnosis by a doctor of a congenital heart defect**
○ yes ○ no ○ unknown ○ not assessed

Hilfe: If a patient has a known congenital heart defect, it will be coded here. Congenital heart defects include shunt defects (e.g. ASD, VSD), congenital valvular heart diseases (e.g. pulmonary stenosis) and cardiomyopathies diagnosed in the first five years of life. Patent foramen ovale does not belong to the class of congenital heart defects

4. Previous cardiovascular interventions

4.1. Interventional coronary revascularization**
○ yes ○ no ○ unknown ○ not assessed

4.1.1. If yes, date of last intervention*
☐ mm.jjjj
○ unknown ○ not assessed

Hilfe: Interventional coronary revascularization is defined as a percutaneously performed intervention on a coronary artery,

e.g. PTCA, stent implantation, rotablation et cetera. Purely diagnostic measures (intravascular ultrasound (IVUS), optical coherence tomography (OCT)) as well as functional measurements (e.g. fractional flow reserve (FFR) measurements) are not interventional coronary revascularization procedures.

4.2. Peripheral revascularization* ○ yes ○ no ○ unknown ○ not assessed

4.2.1. If yes, date of last intervention* [ ] mm.jjjj
○ unknown ○ not assessed

Hilfe: Peripheral revascularization is defined as a percutaneously performed intervention on a peripheral artery (not including coronary arteries or bypass grafts) e.g. PTA, stent implantation, rotablation et cetera

4.3. Coronary bypass operation** ○ yes ○ no ○ unknown ○ not assessed

4.3.1. If yes, date of last intervention* [ ] mm.jjjj
○ unknown ○ not assessed

Hilfe: Coronary bypass operation is defined as operative myocardial revascularization by means of a bypass graft (e.g. from the internal thoracic artery or using arterial/venous grafts). Where applicable, the date of the most recent operation should be entered

4.4. Other vascular operation* ○ yes ○ no ○ unknown ○ not assessed

4.4.1. If yes, date of last intervention* [ ] mm.jjjj
○ unknown ○ not assessed

Hilfe: Other vascular operation is defined as an operation of any kind on non-coronary blood vessels. Where applicable, the date of the most recent operation should be entered

4.5. Heart valve operation** ○ yes ○ no ○ unknown ○ not assessed

4.5.1. If yes, date of last intervention* [ ] mm.jjjj
○ unknown ○ not assessed

Hilfe: Heart valve operation is defined as a minimally invasive percutaneous (catheter-based) or open surgical procedure on a heart valve. This includes the surgical reconstruction/replacement of heart valves, valvuloplasty procedures as well as interventional treatment of heart valve diseases (e.g. dilation, implantation of protheses, heart valve repair).

4.5.2. Type of last intervention* ○ open surgery ○ catheter-based ○ unknown ○ not assessed
If open surgery* ○ replacement ○ reconstruction ○ unknown ○ not assessed

4.5.3. If more than one procedure on one valve was performed, please provide details of the last OP (= current state)*

Aortic valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ TAVI ○ unknown ○ not assessed

○ transfemoral ○ transapical ○ transaortal ○ unknown ○ not assessed

Pulmonic valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ unknown ○ not assessed

Mitral valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ clipping ○ unknown ○ not assessed

Triscuspid valve* ○ native ○ reconstruction ○ mechanical prosthesis ○ bioprosthesis (open) ○ unknown ○ not assessed

4.6. Implanted pacemaker or defibrillator?** ○ yes ○ no ○ unknown ○ not assessed

4.6.1. If yes, what was implanted?* ○ pacemaker ○ defibrillator ○ unknown ○ not assessed

4.6.2. If yes, date of last event (implantation/exchange)* [ ] mm.jjjj
○ unknown ○ not assessed

4.6.3. If pacemaker, please give pacemaker type* ○ 1-chamber pacemaker (e.g. VVI) ○ 2-chamber pacemaker (e.g. DDD) ○ biventricular pacemaker (CRT) ○ unknown ○ not assessed

Hilfe: Implantable cardiac pacemaker or defibrillator is defined as status post implantation of a cardiac pacemaker or cardio-verter defibrillator (ICD)

4.7.	**Other devices***	○ yes ○ no ○ unknown ○ not assessed
4.7.1.	**Cardiac contractility modulation (CCM)***	○ yes ○ no ○ unknown ○ not assessed
4.7.2.	**Intra-aortic balloon pump (IABP)***	○ yes ○ no ○ unknown ○ not assessed
4.7.3.	**Other devices***	

Hilfe: Other devices are defined as other implantable devices for cardiac/vascular support. This includes devices for cardiac contractility modulation, for neuromodulation (e.g. vagus nerve stimulator, baroreceptor stimulator), intra-aortic balloon pumps and left ventricular cardiac assist devices

4.8.	**S.p. myocardial biopsy***	○ yes ○ no ○ unknown ○ not assessed
4.8.1.	**Date of myocardial biopsy***	☐ mm.jjjj ○ unknown ○ not assessed
4.8.2.	**Biopsy sites***	○ left ventricle ○ right ventricle ○ left and right ventricle ○ unknown ○ not assessed

Hilfe: Status post myocardial biopsy is defined as status post bioptic removal of tissue from the heart muscle (e.g. during a right/left catheter examination or operation)

5. Current secondary diagnoses

5.1.	**PAOD****	○ yes ○ no ○ unknown ○ not assessed
5.1.1.	**Fontaine stage***	○ I ○ IIa ○ IIb ○ III ○ IV ○ unknown ○ not assessed
5.1.2.	**Acute ischaemic occlusion***	○ yes ○ no ○ unknown ○ not assessed

Hilfe: PAOD is defined as a current or previous diagnosis by a doctor of peripheral arterial occlusive disease (in the blood vessels of the pelvis and legs, or from the upper extremity of the subclavian artery to the distal extremity). Renal, coronary, cerebral and mesenteric blood vessels and aneurysms are excluded. Possible symptoms are:
- intermittent claudication,
- pain at rest,
- amputation due to severe arterial vascular insufficiency,
- vascular reconstruction, bypass operation or percutaneous revascularization,
- a positive non-invasive test (e.g. ankle-brachial index of ≤ 0.9, pathological TCPO2 measurement, evidence of 50 % or greater stenosis of a peripheral artery by Doppler/duplex sonography, CT, MRT, or angiography)

5.2.	**Stroke/TIA****	○ yes ○ no ○ unknown ○ not assessed
5.2.1.	**Date***	☐ mm.jjjj ○ unknown ○ not assessed
5.2.2.	**Aetiology***	○ ischaemic ○ haemorrhagic ○ unknown ○ not assessed
5.2.3.	**Diagnosis***	○ TIA ○ stroke ○ unknown ○ not assessed
5.2.4.	**Stroke severity***	○ minor ○ major ○ unknown ○ not assessed
5.2.5.	**Consequences of the stroke***	○ disabling ○ non-disabling ○ unknown ○ not assessed

Hilfe: Stroke/TIA is defined as a current or previous diagnosis by a doctor of:
- Ischaemic stroke: Infarction of tissue of the central nervous system, either symptomatic or silent (asymptomatic).
- Transient ischaemic attack (TIA): A transient episode of neurological dysfunction caused by focal brain, spinal cord or retinal ischaemia without acute infarction which resolves completely within 24 hours. This definition is not met by chronic (non-vascular) neurological diseases or other acute neurological diseases such as metabolic or ischaemic encephalopathy resulting from general hypoxia (e.g. in the case of respiratory insufficiency, following a cardiac/circulatory arrest).
- Haemorrhagic stroke: Neurological dysfunction caused by intra-cranial bleeding.
- Stroke where there is uncertainty as to whether the cause was haemorrhagic or ischaemic

5.3.	**Chronic lung disease****	○ yes ○ no ○ unknown ○ not assessed

Hilfe: Chronic lung disease is defined as a diagnosis by a doctor of a chronic lung disease (e.g. COPD, chronic bronchitis, pulmonary fibrosis) and/or their pharmacological treatment, for example, with inhalable or oral pharmaceuticals

5.4.	**Primary pulmonary Hypertension***	○ yes ○ no ○ unknown ○ not assessed

Hilfe: Primary pulmonary hypertension is defined as a diagnosis and/or treatment by a doctor of primary pulmonary hypertension

5.5. Depression**
If the response to this question is "yes", please complete the "Depression" form.
○ yes ○ no ○ unknown ○ not assessed

Hilfe: Depression is defined as a current or previous diagnosis by a doctor. The administration of antidepressants alone does not qualify for a diagnosis of depression

5.6. Cancer more than 5 years ago** ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Cancer more than 5 years ago is defined as a current or previous diagnosis of a malignant cancer. Basal cell carcinoma is not counted as a malignancy

5.7. Cancer within the last 5 years* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Cancer within the last 5 years is defined as malignant cancer diagnosed by a doctor less than 5 years ago. Basal cell carcinoma is not counted as a malignancy

6. Blood pressure after 5 minutes at rest

6.1. Systolic**
☐ mmHg
○ unknown ○ not assessed

6.2. Diastolic**
☐ mmHg
○ unknown ○ not assessed

Hilfe: The systolic blood pressure should be measured using a blood pressure monitor that is serviced and calibrated on a regular basis. Where possible, tested devices should be used for epidemiological trials. Blood pressure measurement begins after the patient has been at rest for at least 5 minutes. Three readings are taken at intervals of 2 minutes; the average values of the second and third readings are entered into the CRF

7. Heart rate after sitting down for 5 minutes

7.1. Heart rate**
☐ per minute
○ unknown ○ not assessed

Hilfe: Measurement of the heart rate begins after the patient has been sitting down for at least 5 minutes. This should take place after measuring the blood pressure. This should be done manually by counting the radial pulse for 30 seconds; that value multiplied by two should be entered into the CRF (beats/minute)

8. Further diagnoses

8.1. Dyspnoea on exertion* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of shortness of breath with physical exertion within the last 14 days and/or at present

8.2. Dyspnoea at rest* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of shortness of breath even when at rest (e.g. when talking) within the last 14 days and/or at present

8.3. Peripheral oedema* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: A patient who complains of bilateral accumulation of fluid in the extremities within the last 14 days and/or at present, whether clinically observed or perceived by the patient

8.4. Jugular venous distention* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: The diagnostic test for jugular venous distention is conducted with the upper body of the patient positioned at a 45° angle

8.5. Pulmonary rales* ○ yes ○ no ○ unknown ○ not assessed

Hilfe: Pulmonary rales are defined as sounds heard over the lung during auscultation which are created by the movement of fluids and/or secretions during inspiration and expiration. They belong to the category of adventitious breath sounds overlying normal breath sounds and indicate a pathological change in the lung

9. Laboratory diagnostics (blood)

For clinically stable patients, not more than 1 week old, otherwise up to date!

9.1.	**Date blood sample was taken****	☐ tt.mm.jjjj Where applicable, give date for the latest value ○ unknown ○ not assessed
9.2.	**Haemoglobin****	☐ ○ unknown ○ not assessed
	Unit**	○ mmol/l ○ g/dl
9.3.	**Creatinine (serum, heparin plasma)****	☐ ○ unknown ○ not assessed
	Unit**	○ µmol/l=nmol/ml ○ mg/dl
9.4.	**Total cholesterol****	☐ ○ unknown ○ not assessed
	Unit**	○ mmol/l ○ mg/dl

10. The next three anamnestic questions are for women only

10.1.	**Menopause?****	○ yes ○ no ○ unknown ○ not assessed
10.1.1	**Year of menopause****	☐ jjjj ○ unknown ○ not assessed
10.2.	**Day last menstrual period began****	☐ tt.mm.jjjj ○ unknown ○ not assessed

Mögliche Angaben

Bitte wählen Sie bei den oben mit Anmerkungen versehenen Feldern eine der hier aufgelisteten Angaben.

1)

1
2
3

Biobanking Basic Set (DZHK-SOP-B-02)

The module Biobanking Basic Set is used to document the quality of samples of the Basic Set. The Basic Set consists of EDTA plasma, serum, citrate plasma, buffy coat and urine.

The processing and storage of the material ought to be performed according to DZHK-SOP-B-02.

DZHK-SOP-B-02:
- Version V1.1
- Valid as of: 15.12.2014
- https://dzhk.de/en/resources/sops/

The corresponding secuTrial® form is only available in German.
State of the attached secuTrial® form: 14.07.2020

Biomaterial-Begleitschein Basis-Set (9.6.)

1. Basis-Set (Allgemeine Informationen)

1.1.	**Biomaterial-ID Basis Abnahmeset**	☑ ☐
1.2.	**Studie**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
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1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐
1.3.	**Einrichtungscode**	☐

2. Blut- und Urinprobe

2.1.	**Blutentnahme durch**	☐
2.2.	**Zeitpunkt der Blutentnahme**	☐ tt.mm.jjjj hh:mm
2.3.	**Blutentnahme**	○ venös ○ arteriell ○ unbekannt ○ nicht erhoben
2.4.	**Position bei Blutentnahme**	○ sitzend ○ liegend ○ unbekannt ○ nicht erhoben
	Dauer der Position des Patienten/Probanden vor Entnahme:	☐ min. ☐ ≥ 60 min.
2.5.	**Zeitpunkt der Urinabgabe (Klinik)**	☑ ☐ tt.mm.jjjj hh:mm
2.6.	**Abstand zur letzten Nahrungsaufnahme**	○ < 8 Std. ○ >= 8 Std. ○ unbekannt ○ nicht erhoben
	Wenn bekannt, bitte die Gesamtstunden angeben	☑ ☐ Std.
2.7.	**Ernährung parenteral**	○ ja ○ nein ○ unbekannt ○ nicht erhoben
2.8.	**Menstruation bei Uringewinnung (bei Frauen)**	○ ja ○ nein ○ unbekannt ○ nicht erhoben
	Neue DZHK Basis-Sets (bestellt ab Januar 2020) enthalten nur noch je 1 Primärröhrchen.	
2.9.	**Anzahl gefüllter Primärgefäße**	

Serum	○0 ○1 x 10 ml
EDTA-Plasma	○0 ○1 ○2 (BD)
Citrat-Plasma	○0 ○1 ○2
Urin	○0 ○1

2.10. Zeitpunkt Eingang im Labor

Datum und Uhrzeit	☑ [ ] tt.mm.jjjj hh:mm
Ansprechpartner	☑ [ ]
Wenn Urin-Eingang unterschiedlich von Blut:	☑ [ ] tt.mm.jjjj hh:mm
Ansprechpartner	☑ [ ]

2.11. Ende der Zentrifugation

Datum und Uhrzeit	☑ [ ] tt.mm.jjjj hh:mm
wenn Urin-Eingang unterschiedlich von Blut, hier bitte Zeiten für Urin eintragen:	☑ [ ] tt.mm.jjjj hh:mm

2.12. Probenbeschaffenheit (Blut)

Ist die Probenbeschaffenheit unauffällig?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit lipämisch?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit ikterisch?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit hämolytisch?	○ja ○nein ○unbekannt ○nicht erhoben

2.13. Probenbeschaffenheit (Urin)

Ist die Probenbeschaffenheit unauffällig?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit trüb?	○ja ○nein ○unbekannt ○nicht erhoben
Ist die Probenbeschaffenheit blutig?	○ja ○nein ○unbekannt ○nicht erhoben

2.14. Anzahl gefüllter Aliquotgefäße

Alle 10 Serumgefäße [300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 10)
Alle 10 EDTA-Gefäße [300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 10)
Alle 4 Citrat-Gefäße [300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 4)
Alle 8 Urin-Gefäße [300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 8)
Alle 2 Buffy Coat-Gefäße [<300µl] gefüllt?	○ja ○nein ○unbekannt ○nicht erhoben
Falls nicht, bitte spezifizieren	☑ [ ] (max 2)
Kommentar	[ ]

2.15a. Zeitpunkt Einfrieren der Aliquot [ ]

	(s) bei -80°C bei Zwischenlagerung am Studienzentrum	
	Datum und Uhrzeit	☑ tt.mm.jjjj hh:mm
	Ansprechpartner	☑
2.15.	**Zeitpunkt Einfrieren aller Aliquots bei -80°C (Serum, EDTA-Plasma, Citrat-Plasma, Urin, Buffy Coat)**	
	Datum und Uhrzeit	☑ tt.mm.jjjj hh:mm
	Ansprechpartner	☑

3. Besonderheiten

Cardiac Catheter (DZHK-SOP-K-05)

The module Cardiac Catheter is used to document a cardiac catheter examination. This examination enables a better phenotyping of cardiomyopathies, an assessment of the degree of severity and of the prognosis.

The examinations ought to be performed according to DZHK-SOP-K-05.

DZHK-SOP-K-05:
- Version V1.0
- Valid as of: 01.09.2014
- https://dzhk.de/en/resources/sops/

State of the attached secuTrial® form: 13.07.2020