



DZHK-SOP-TTP01

Acquisition of
person identifying data
and the informed consent

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1 List of Abbreviations

Abbreviation	Plain text
SOP	Standard Operating Procedure
DZHK	Deutsches Zentrum für Herz-Kreislauf-Forschung e.V. (German Centre for Cardiovascular Research)
IDAT	Person Identifying data (name, address, date of birth, ...)
PSN	Pseudonym
TTP	Independent Trusted Third Party
IC	Informed Consent
LfdI M-V	State Data Protection and Freedom of Information Office of Mecklenburg-Western Pomerania
SC	DZHK study centre

2 Change to the previous version

- change of contact information of the TTP
- Description of the new functionalities: “upload new IC Scan” and “register new IC”

3 Introduction

This SOP outlines the procedures for the scenarios *Acquisition of person identifying data (IDAT) and the Informed Consent (IC)* and *Editing contact information of participants* for clinical research within the Central Data Management (CDM) infrastructures at the DZHK.

This SOP is based on the data protection concept of the DZHK's Central Data Management (version 1.1 of 27/08/2013).

The Independent Trusted Third Party of the DZHK's Central Data Management (TTP) can equally process identifying data of patients and participants. To ensure uniformity in the spoken and written form, the term *study participant* will be used. The term applies to both genders equally.

3.1 Objective

The purpose of this SOP is to define the procedural workflows for recording and editing person identifying data (IDAT) of a study participant as well as the respective informed consent (IC).

3.2 Target group

This SOP shall apply to the study staff involved in clinical studies of the DZHK ("you").

3.3 Scope

The SOP is valid for the sum of all clinical research projects conducted in the DZHK.

4 Background

Processing of IDAT is the responsibility of the Independent Trusted Third Party which is located at the University Hospital in Greifswald. Data processing is thus subject to the provisions of the State Data Protection Act of Mecklenburg-Western Pomerania.

The technical, personnel, spatial and organisational measures that are essential for ensuring the necessary framework conditions were defined in a data protection concept that was discussed with the State Data Protection and Freedom of Information Officers of Mecklenburg-Western Pomerania (LfDI M-V) and for which a positive vote was issued.

5 Requirements and conditions

5.1 General requirements

- The study participant has provided positive consent in writing.
- You are authorised to use the secuTrial system.

5.2 Technical requirements

- Only devices that meet the administrative regulations for IT and information security and that are subject to the update management of the SC may be used for digitally recording data in the study centres of the DZHK (SC).
- The applications are protected by up-to-date safety procedures. For this reason it is mandatory to always use the most recent version of an internet browser. The following browser versions meet the minimum requirement stipulated by the LfDI M-V:
 - Firefox from version 26
 - Internet Explorer from version 8 under Microsoft Windows 7
 - Chrome from version 32
- The client certificate of the TTP was installed in the browser being used.

5.3 Technical conditions

- Open the application only once. Do not open the application in multiple tabs of the same browser window, nor in multiple browser windows at the same time.
- It is not permitted to go backwards or forwards using the browser function ("back button").
- It is not permitted to update the forms using the browser's update function.
- Follow the instructions provided in the respective web forms.

6 Processes

Under normal circumstances, a study participant is recorded by registering the study participant in the TTP for the first time following these 2 steps: *Acquisition of IDAT* and *acquisition of the IC*. There are two special cases in addition to the normal case. First, the study participant may already be registered in the TTP and second, a study participant with very similar IDAT may already exist in the TTP. The workflows for processing the three possible cases of recording IDAT are illustrated in Figure 1.

Furthermore, it is possible to edit the contact details of a study participant and to display the currently valid consent. Moreover, it is also possible to add a new IC scan (paper based informed consent) to an existing electronic IC or to register a new electronic IC with associated scan.

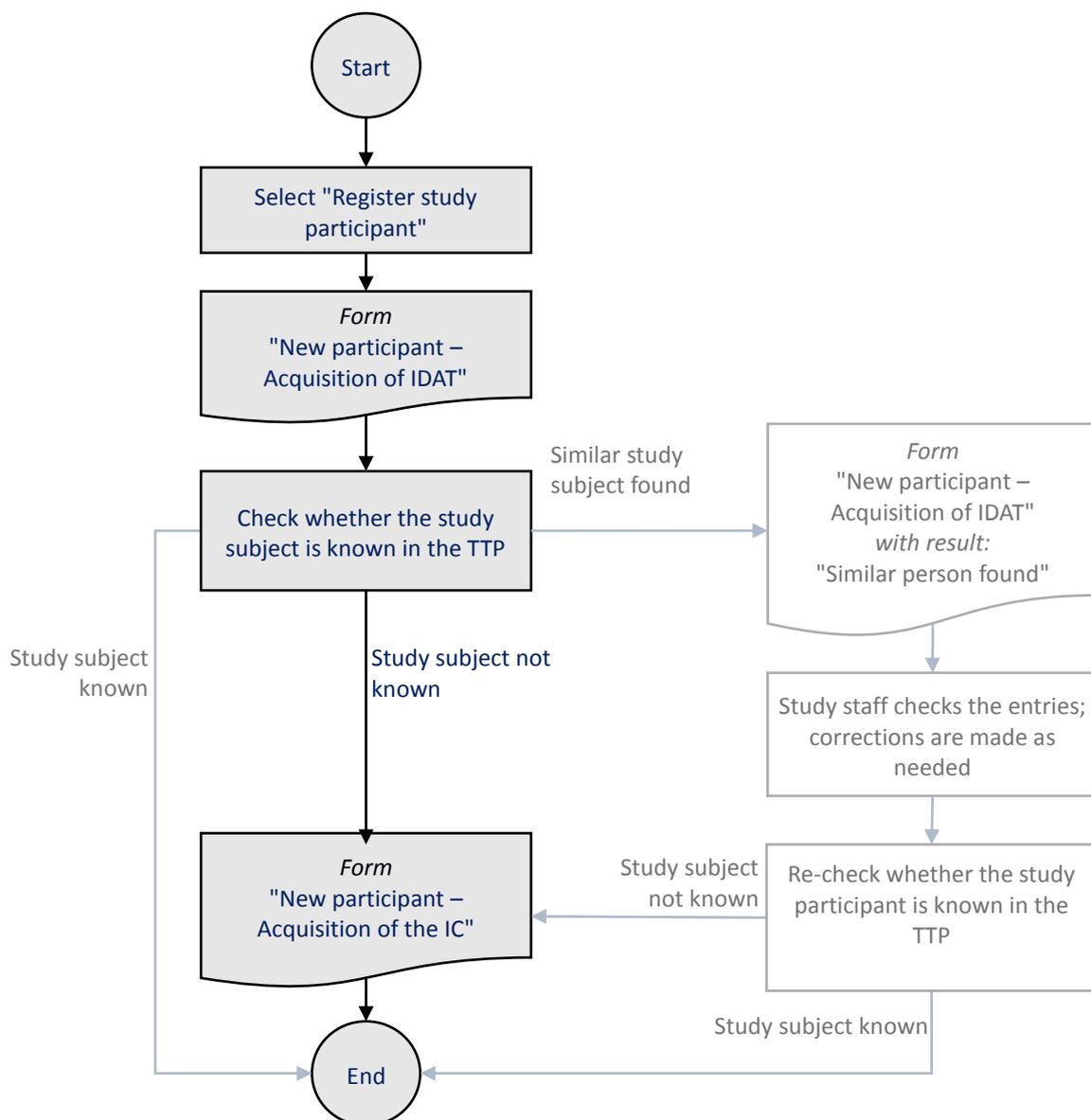


Figure 1: Workflow for registering a study participant

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6.1 Registering a new study participant

If you wish to register a study participant, start this process via the menu item *New patient* in the top right corner of the application *secuTrial*. Select the respective project. You will then be asked to enter the registration date. Enter the date and confirm the entry by clicking on *Continue*. At this point you may have to select your Client Certificate (for more details about the Client Certificate please read the [Information leaflet Client Certificate](#)). Next you will be given instructions on how to register a new study participant. Read the instructions and confirm that you have read them by clicking on *Continue*.

The form *New Participant - Acquisition of person identifying data (IDAT)* will then be opened (see Figure A- 1: Acquisition of person identifying data (IDAT)). Complete this form and make sure that you fill out the mandatory fields (marked with an asterisk). Table 1 provides a description and examples of the various fields contained in the form.

After filling out the form, please check your entries once more and confirm them by clicking on *Continue* to get to the next step. In the next step, the TTP will check whether the entered study participant is already known.

Table 1: Instructions for entering identifying data

Field name	Mandatory field	Description	Examples
Surname	X	Enter only the study participant's current surname without a title or form of address. Enter the name at birth or the maiden name into the separate field <i>Maiden Name</i> . If necessary, separate double surnames with a hyphen.	Miller Miller-Schmidt
First name	X	Enter all known and valid first names . If the study participant has multiple first names, enter them all. It is not permitted to enter nicknames or pseudonyms.	Julia Edward-Cornelius
Maiden Name	-	If the study participant has a maiden name that is different from the surname, enter the name at birth into this field. Separate double surnames with a hyphen.	Miller Miller-Schmidt
Date of birth	X	Enter the study participant's date of birth using only digits. The first two digits represent the day, the second two digits the month and the last four digits the year (DD.MM.YYYY).	25.11.1985
Place of birth	X	Enter the study participant's place of birth .	
Gender	X	The study participant's gender is entered by selecting one of the options from the drop-down menu.	male female other
Street	X	Enter the current street name and house number of the study participant's officially registered primary residence. Pay attention to the following: 1. Enter <i>only one space</i> between the street name and house number. 2. If the house number is followed by a letter, again	Baker Street 17 Boulevard de Palais 6 a Rua Sao Lazaro 33

Field name	Mandatory field	Description	Examples
		separate it using <i>only one space</i> . 3. Enter house number ranges with a <i>hyphen</i> or a <i>slash</i> .	
Place of residence	X	Enter the place of the study participant's officially registered primary residence.	
Zip code	X	Enter the zip code of the study participant's officially registered primary residence.	
Telephone number	-	If the study participant gives his consent for his telephone number to be entered, enter it into this field. Enter the telephone number without the country code, but include the prefix and the participant's telephone number. Only digits may be entered. Spaces and hyphens for grouping the numbers are optional.	030 12345-67 0123 456 789
Email address	-	If the study participant gives his consent for his email address to be entered, enter it in full in small letters and with only one @ sign.	email@example.com

6.2 Checking whether the entered study participant is already registered in the TTP

If the IDAT were entered in full and in the correct format, in the next step the system checks automatically whether the study participant is already registered in the TTP. This check can produce the following results (see Figure 1):

- The study participant is not known in the TTP (→6.3)
- The study participant is known in the TTP (→6.4.1)
- The TTP contains a study participant with similar IDAT (→ 6.4.2)

6.3 Acquisition of the Informed Consent (IC)

Once you have registered a new study participant and if the subject is not registered in the TTP yet, a new form to record the IC will be displayed (see Figure A- 2).

In this form you will be asked to electronically record the study participant's consent. This is done in two steps that are outlined below:

1. Completion of the electronic form *New Participant - Acquisition of the Informed Consent*
2. Transfer of the paper-based consent as a digital copy (scan) to the TTP

6.3.1 Recording the paper-based consent in the electronic form

Start by comparing the version number of the displayed electronic form with the version of the paper-based consent. These version numbers must be identical! Should this not be the case, ask the study participant to complete the paper-based consent in the correct version again. If the potential study participant does not agree to provide a new consent, he will no longer be allowed to take part in the study.

Fill out the fields of the electronic form based on the study participant's paper-based consent form. Check the entries one more time and compare them with the entries on the paper-based consent form. If the data you entered is identical to the stored informed consent form, in a final step confirm the data by ticking the box *I hereby confirm...* and clicking on *Continue*.

This concludes the registration of the study participant in the TTP, following which the pheno-pseudonym (PSN) is generated for this patient and displayed. Enter the PSN into the respective field on the paper-based consent form. Furthermore, the pseudonym for the biosamples (LIMS pseudonym) will also be displayed; please also note down this number (see Figure A- 3).

To ensure that the study participant's data can be used within the scope of the informed consent, you have to send a digital copy (scan) of the paper-based informed consent to the TTP. Until the TTP has received a copy of the informed consent form, the study participant's data cannot be used for the data transfer/access/utilisation process in accordance with the terms of use of the DZHK.

Note: If your study wants to use informed consents consisting of multiple parts, the page for acquisition of the informed consent will be displayed several times. Make sure that you always transfer the correct part. For informed consents consisting of multiple parts, individual parts of the consent may be optional. Should the participant not have completed an optional part, you can skip the recording for this part.

6.3.2 Transferring the scanned paper-based consent form to the TTP

Prior to scanning the document, make sure that you have entered the study participant's generated pheno-PSN in 6.3.1 into the corresponding field. Scan the paper-based consent form using a suitable device (e.g. scanner or copy machine with a scanner function) in preparation for sending a digital copy of the consent form. Store the scan in PDF format.

If the TTP has not received a valid scan of the study participant's original consent form within two months, the requirement for consent of the State Data Protection Officer cannot be met; any previously entered data will be blocked in the Consent Management of the TTP and eCRF in secuTrial and will no longer be available for the data utilisation process in accordance with the terms of use of the DZHK.

You can use any of the options (a)-(c) outlined below for transferring the scanned consent form.

(a) Upload the scan in the electronic form

This is the preferred way of transferring the scan. To use this option, the scan must be available in PDF format.

After you have successfully registered a new participant (see section 6.3.1), select the scanned PDF document in the form *New participant – Upload scan and submit* by clicking on *Select scan(s)* (Figure A-3). If the copy of the informed consent form consists of multiple PDF files (e.g. front page, reverse), you have the option of selecting and uploading multiple PDF documents. By clicking on *Upload*, the PDF document will be transferred to the TTP. The TTP will check immediately whether the PDF file is valid, and if applicable, a negative check result will be displayed. If this is the case, please review the contents of the uploaded document by clicking on *Preview*.

Note: If you have uploaded one or more incorrect documents by accident, you can delete previously uploaded files by clicking on *Delete* (icon: recycle bin) and repeating the selection process. End the process *New participant* by clicking on *Save participant*.

(b) Subsequently transferring scans by the functionality “Edit basic data and IC”

First of all, you have to select the Pheno-PSN of the study participant in the search field of secuTrial (top right). Then, use the Button “Edit basic data and IC”. You will be informed about the process of

editing data of participants. Read the information and conclude with *continue*. After that, the web form “Edit participant” will appear.

The tab “Consent Management” (see Figure A- 6) enables you to check the currently stored ICs for the selected participant. By clicking on the “plus-icon” in column “Scans”, a Popup-window (see Figure A- 7) will be opened. Choose the correct IC-scan for the participant and click “Append scan”.

6.4 Special cases for registering a study participant

6.4.1 The study participant is registered in the TTP

If a study participant is already registered in the TTP with the entered IDAT, a corresponding alert as well as the PSN of the subject will be displayed. In this case it is not necessary for you to record the IC and the registration of the study participant is concluded. Click on *Finish* to end the process.

If you are absolutely sure, that the entered participant has not been registered before in your SC, please contact the TTP.

6.4.2 The TTP contains a study participant with similar IDAT

If the TTP check finds a study participant whose IDAT are similar to the IDAT entered, you will be shown the alert *A person with similar details already exists (first name, surname, gender, date of birth and place of birth)*. (see Figure A- 4).

Review the values you entered. **Make sure there are no spelling mistakes!** If you notice a mistake, please correct your entry.

Confirm the entries by clicking on *Continue*. The system will run another data check and will either forward you to the form for acquire the IC (cf. 6.3 Acquisition of the Informed Consent (IC)) or will show you the PSN if the subject already exists (cf. 6.4.1 The study participant is registered in the TTP).

6.5 Editing participants identifying information and ICs

To watch and edit the information and ICs of a participant, you first have to enter the pheno-pseudonym in the search field of secuTrial (top right). Then, use the Button “Edit basic data and IC”. You will be informed about the process of editing data of participants. Read the information and conclude with *continue*. You will be then be led to the form “Edit participant”.

6.5.1 Edit contact data

In the tab "Participant data" (see **Fehler! Verweisquelle konnte nicht gefunden werden.**) you can view the IDAT that were entered when the person was registered. Here you have the opportunity of editing the contact details by clicking on *Edit*, such as the person’s street name, place, zip code, telephone number and email address. If you want to save the changed information, click on *Save*.

6.5.2 Edit IC and IC-Scan

By clicking the tab “Consent Management” you can see the latest IC-Scan (*eye-icon* in the column *Scan*) or upload a new IC-scan (plus-icon in the column *Scan*, see 6.3.2(b) Subsequently transferring scans by the functionality “Edit basic data and IC”).

6.5.3 Add a new IC with IC-Scan

By clicking the tab “Consent Management” (see Figure A- 6) you can register a new IC with IC-scan by clicking on the Button “New consent”. A Popup-window will be opened. At first, choose the correct version of the IC. Afterwards the chosen IC will be displayed. Continue by following the instructions under section 6.3 (page 7). Do not forget to choose the correct IC-scan at the end of the process (see Figure A- 8). You will finish the process by clicking on *Save consent*.

7 Responsibilities

7.1 Study centre

The SC is the sole point of contact for all questions concerning the IDAT and informed consent form for the study participants.

7.2 Independent Trusted Third Party

The TTP is responsible for providing and for ensuring the correct functionality of the application and for processing the data in accordance with the data protection vote of the LfDI M-V.

Contact details of the Independent Trusted Third Party

Unabhängige Treuhandstelle des DZHK
an der Universitätsmedizin Greifswald
Institut für Community Medicine, Abt. VC
Ellernholzstr. 1-2
17487 Greifswald

Tel.: +49 (0)3834/86-7588

Email: ths-dzhk-support@uni-greifswald.de

8 Literature / sources

- Data protection concept of the TTP of the DZHK's Central Data Management (version 1.1 of 27/08/2013)
- State Data Protection Act - DSG M-V (version of 28/03/2002)
www.landesrecht-mv.de
- Hospital Law for the State of Mecklenburg-Western Pomerania
www.landesrecht-mv.de

9 Persons involved in creating the SOP

Name	Role	Involvement
Torald Weihs	Medical Data Manager	Author
Dirk Langner	IT Research Associate	Author
Thomas Bahls	Scientific Project Coordinator	Reviewer
Katrin Leyh	Medical Data Manager	Author
Dana Stahl	Research Associate	Reviewer

10 Applicable documents

- DZHK-SOP-THS-11_EN_Ticketsystem in the current version
- Data protection concept of the TTP of the DZHK's Central Data Management (version 1.2 of 24/03/2014)
- Ethics concept of the Clinical Research Department of the Deutsches Zentrum für Herz-Kreislauf-Forschung e.V. (DZHK) (version 2.0 of 01/02/2016)

11 Annex

DZHK
DEUTSCHES ZENTRUM FÜR
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Test System

Community Medicine

New participant - Acquisition of person identifying data (IDAT)

◦ Mandatory fields are marked with *

Last name *

First name *

Maiden name (if different)

Date of birth (TT.MM.JJJJ) *

Place of birth *

Gender *

Street (incl. house number) *

City *

Postcode *

Telephone

Email

[Clear fields](#)

English

DZHK Trusted Third Party, Greifswald, Version: 1.0.0-SNAPSHOT (T)

Figure A- 1: Acquisition of person identifying data (IDAT)

New participant - Registration of informed consent

- o Copy the information from the consent document into the shown form.
- o By submitting the form with the button „Continue“ he will be saved at the Independent Trusted Third Party of the DZHK and a pseudonym will be generated.

[Print view of personal data from participant](#)

Informed Consent
Intravenous Iron in Patients with Systolic Heart Failure and Iron Deficiency to Improve Morbidity and Mortality (FAIR-HF2) , Version 1.1

I have been informed by the responsible investigator or one of his representatives orally and in writing about the nature, significance, and scope of this clinical trial as well as about my rights and obligations as a trial participant. I had [\[more\]](#)

I am aware that personal data about me, especially medical findings, are to be recorded, stored, and evaluated in this clinical trial. The use of the data is subject to legal regulations and requires the following voluntary declaration of consent before participating in the clinical trial, i.e. I cannot participate in the clinical trial without giving the following consent.

1. I agree that during this clinical trial, personal data about me, especially data on my health and my ethnic origin, will be collected and recorded in paper form and on electronic data carriers at the trial site and by the DZHK central data management. If required, the collected data may be transferred in pseudonymised (coded) form as described in the information sheet: a) to the sponsor or a party authorised by the sponsor for the purpose of scientific evaluation (also into countries with a lower data protection level), b) to scientific projects within the scope of the DZHK Use and Access Policy, c) in case of an application for licensing: to the applicant and to the authority responsible for licensing, the Federal Institute for Drugs and Medical Devices (BfArM), d) in case of adverse events: to the sponsor or a party authorised by the sponsor, to the competent ethics committee, and to the competent higher federal authority, the Federal Institute for Drugs and Medical Devices, as well as from the latter to the European Database. 2. I further agree that representatives authorised by the sponsor who are sworn to secrecy and the competent supervisory authorities may access my personal data, especially my health information, held by the investigator insofar as this is necessary to verify the proper conduct of the trial. For this purpose, I release the investigator from medical confidentiality. 3. I have been informed that I can end the participation in the clinical trial at any time. However, the consent to the collection and processing of my personal data, especially the information about my health, is irrevocable. I know that in case I revoke my participation in the clinical trial, the data stored up to this time may continue to be used insofar as this is necessary to a) identify effects of the investigational medicinal product, b) ensure that my interests meriting protection are not violated, c) fulfil the obligation to submit complete licensing documents. In case of revocation, my medical information will only be transferred to scientists for research projects in anonymised form. 4. I agree that my data will be stored for at least ten years after conclusion or termination of the trial and that they will continue to be used and transferred for

Figure A- 2: Acquisition of the Informed Consent

New participant - Upload scan and submit

• Please execute the following steps to complete

The secuTrial-pseudonym for the participant is: **pheno_051242013**

The LIMS-pseudonym for the participant is: **lims_557021983**

[Print view of personal data from participant](#)

1. Enter the pseudonym **pheno_051242013** in the field „Pseudonym at DZHK (secuTrial)“ on the paper-based consent.
2. Scan the paper-based consent (including pseudonym) as one PDF document.
3. Transmit the PDF document to the DZHK Trusted Third Party described as follows:
 - Select the PDF documents with the button „Scan(s)“
 - Check your selection
 - Click on the button „Upload“
 - Verify the result afterwards with the button „Preview“

Hint: If any correction is required, repeat step 3.

Einwilligungserklärung
TranslatiOnal Registry for Cardiomyopathies (TORCH), Version 2.0

No scan was uploaded yet.

4. By clicking the button „Save participant“, the uploaded scans will be saved and the pseudonym will be transferred into secuTrial.

Figure A- 3: Upload scan and submit

New participant - Acquisition of person identifying data (IDAT)

o The participant may already exist. Please check your inputs and correct them if necessary. Continue afterwards.

 **A person with similar identifying data already exists (First name, Last name, Gender, Date of birth and Place of birth).**

Last name *	<input type="text" value="Holmes"/>
First name *	<input type="text" value="Sherlock"/>
Maiden name (if different)	<input type="text"/>
Date of birth (TT.MM.JJJJ) *	<input type="text" value="05.04.1954"/>
Place of birth *	<input type="text" value="London"/>
Gender *	<input type="text" value="male"/>
Street (incl. house number) *	<input type="text" value="Baker Street 221 B"/>
City *	<input type="text" value="London"/>
Postcode *	<input type="text" value="NW16XE"/>
Telephone	<input type="text"/>
Email	<input type="text"/>

Cancel

Continue 

Figure A- 4: Acquisition of IDAT - A person with similar details already exists

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Test System

Community Medicine

Edit participant

- On this page you can edit the contact data.
- Mandatory fields are marked with *

Identifying data Consent management

Last name *	edöjblk
First name *	wqälvkh
Maiden name (if different)	
Date of birth (TT.MM.JJJJ) *	01.01.1970
Place of birth *	xsxj
Gender *	male
Street (incl. house number) *	<input type="text" value="sytn 33"/>
City *	<input type="text" value="aerha"/>
Postcode *	<input type="text" value="33345"/>
Telephone	<input type="text"/>
Email	<input type="text"/>

English

Independent Trusted Third Party of the DZHK, Greifswald. Version: 1.7.5 (T)

Figure A- 5: Editing contact details

Edit participant

- o On this page u can view and download the current consent documents.
- o Hint: In a future release it will be possible to upload scans afterwards and fill out new consents. Until then please contact the Independent Trusted Third Party of the DZHK Support for these tasks.

Identifying data Consent management

New consent

Date ▾	Consent ⇅	Version	Scan
09:52:19 20.09.2016	TORCH_Einwilligungserklärung CONSENTED	2.0	 

 Back  Finish

Figure A- 6: Displaying the IC and IC scan and downloading the scan.

Append scan *





Figure A- 7: Choose an IC-scan to append

Scans

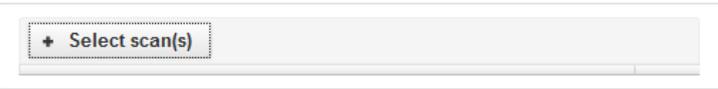
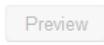
 

Figure A- 8: Choose an IC-scan for post capturing