

DZHK-SOP-TTP-11

Requesting and submitting tickets

Version: 1.2

Valid from: 20/07/2016

Replaces version: 1.1

Dated: 21/10/2015

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1 Lists

1.1 List of Abbreviations

| Abbreviation | Plain text |
|--------------|---|
| DZHK | Deutsches Zentrum für Herz-Kreislauf-Forschung e.V. (German Center for Cardiovascular Research) |
| IC | Informed Consent |
| IDAT | Person identifying data (name, address, date of birth, ...) |
| QM | Quality Management |
| SOP | Standard Operating Procedure |
| SC | DZHK study centre |
| TTP | Independent Trusted Third Party |
| CDM | Central Data Management |

1.2 List of Figures SOP

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2 Change to the previous version

- Upgrade of the SOP to include the scenario "Submitting a download ticket"
- Renaming in Independent Trusted Third Party
- Editorial modifications

3 Introduction

This SOP outlines the procedure for the scenario *Requesting an upload ticket, Submitting an upload ticket and Submitting a download ticket* using the ticket system for clinical research within the infrastructures of the DZHK's Central Data Management (CDM).

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

In this document, the masculine form is used to refer to persons. However, both male and female employees and study coordinators are meant equally.

4 Objective

The aim of the SOP is to define the procedural workflows for ensuring a safe exchange of documents via the ticket system of the TTP. For example, this may be necessary if a previously uploaded and stored IC is found to have issues during the quality management and has to be corrected by the SC or if no IC was uploaded when registering a study participant. Another scenario would be the transfer of the completed revocation form after making use of the right to revoke consent.

4.1 Target group

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

4.2 Scope

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

4.3 Background

When registering a study participant in the TTP forms embedded in secuTrial, the employees of the SC are obliged to upload the ICs. If a TTP employee notices any special features requiring action during the quality management (or if no IC was uploaded), the IC has to be corrected and transferred to the TTP. This function of subsequently transferring documents is not yet available in secuTrial.

If a subject revokes/is excluded from the study, this is recorded on the respective form and sent to the SC for archiving in the study participant's folder. Because this form contains IDATs, the TTP developed the ticket system to ensure a safe exchange of documents containing IDATs.

5 Requirements and conditions

5.1 General requirements

- Email from the TTP support with ticket ID and corresponding PIN
- The ticket was not submitted yet

5.2 Technical requirements

- The ticket can only be submitted on a computer on which the Client Certificate of the TTP was installed

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!
- Follow the instructions provided in the respective forms. It is not permitted to go backwards or forwards using the browser function ("back button")!

6 Processes

6.1 Upload ticket

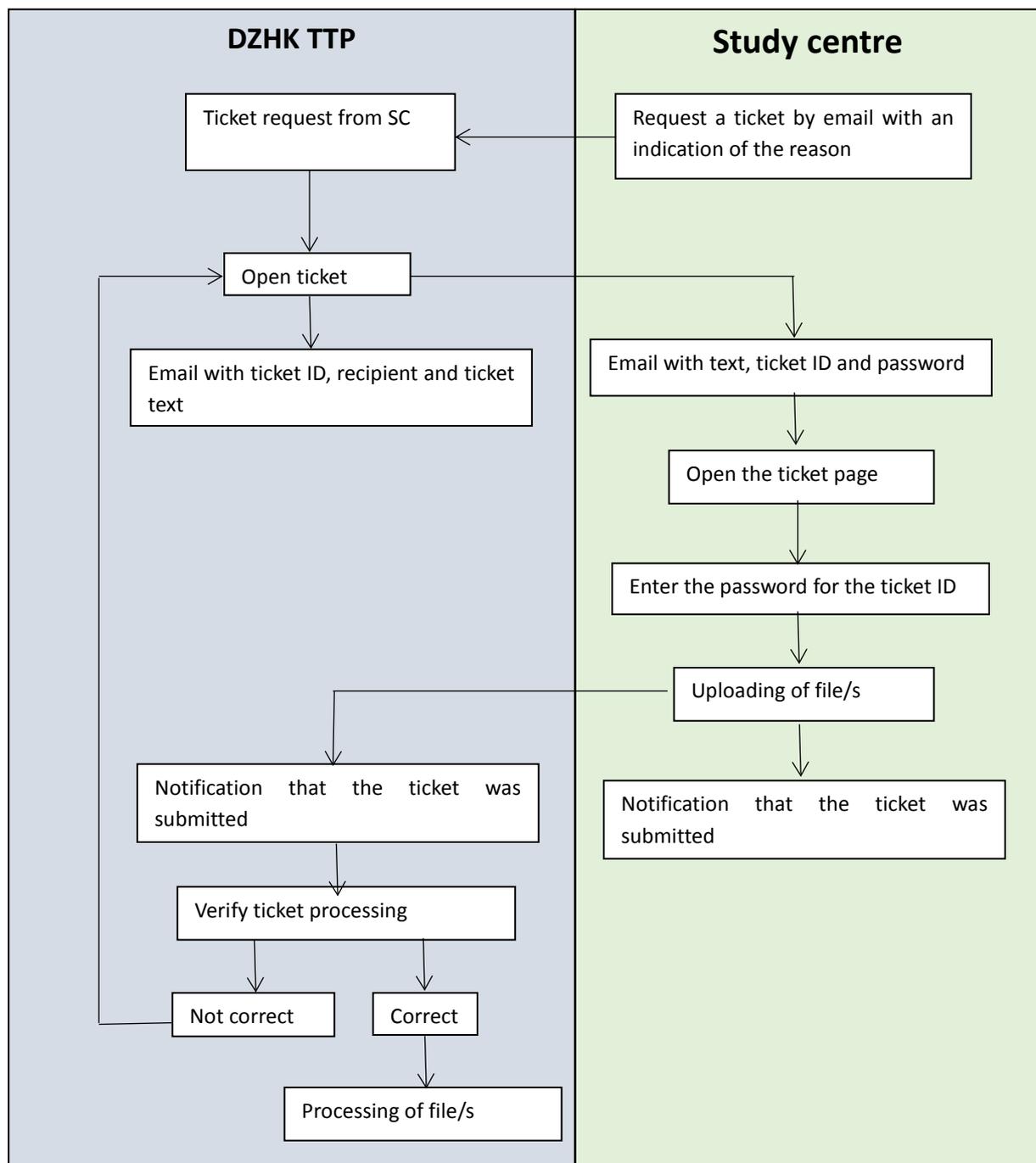


Figure 1: Flowchart for opening and processing an upload ticket

SC can use upload tickets to transfer documents to the TTP in conformity with the data protection provisions. There are two cases in which an upload ticket can be opened. Either the SC itself requests an upload ticket (see section 6.1.1) or the TTP generates a ticket independently of a request. Only case 1 is covered in this SOP.

The SC can submit an upload ticket by uploading one or more documents (each <2 MB). A comment can also be included. Once the ticket has been successfully submitted/closed, a TTP employee can download the documents. The SC receives a confirmation email. The workflows are illustrated in Figure 1 and are outlined in this section.

6.1.1 Upload ticket request from the study centre

If you need an upload ticket, please send an email to ths-dzhk-support@uni-greifswald.de. Please enter "Ticket request" as a subject. The email should contain the following information:

- Reason for request
- Pseudonym of the study participant (for IC)

A possible reason for requesting a ticket could be that you were unable to upload the IC while registering the study participant in secuTrial.

Please make sure not to use any graphical elements in the email (e.g. in the signature). Graphical elements prevent the ticket request from being processed automatically. Manual processing is then required, which in turn can lead to a considerable delay in processing.

6.1.2 Submitting an upload ticket

Click on the link in the email to submit an upload ticket. An example of an email is provided in annex Figure A- 1. After entering the PIN (see annex Figure A- 2) you will be forwarded to the TTP page for uploading files (see Figure 2). To display the content of the upload ticket, simply click on the plus symbol in "Content of the ticket respectively e-mail". To select a file, click on "Choose file(s)" and then on "Upload". *Please make sure not to use any IDATs in the file name, only the pseudonym.* After that you will be shown the files you uploaded. You also have the option of including a comment. End the process by clicking on "Finish".

Upload files to the Trusted Third Party

◦ Here you can upload one or more files to the Trusted Third Party

Ticket-Number: 1634

Ticket from: Maja Mustermann

+ Content of the ticket respectively the e-mail

Please add all documents to the list and press 'Upload' to upload these documents. You can repeat the process if you did accidentally choose wrong documents. The previously uploaded documents will be discarded.

+ Choose file(s) ↗ Upload ⊖ Clear list

1.pdf 23.2 KB ✕

| Filename | Filesize (KB) | Action |
|-------------------|---------------|--------|
| No records found. | | |

Here you can leave any comment you have regarding to the uploaded documents

✕ Cancel ✓ Finish

Figure 2: Page for uploading files to the TTP

The ticket **cannot** be submitted a second time. The ticket is also invalid if you click on "Cancel", and a new ticket then has to be requested.

If you have successfully submitted the ticket (see Figure A- 3), you will receive a confirmation email showing the content of the ticket and a list of transferred files (see Figure A- 4).

6.2 Download ticket

A download ticket is a method through which the TTP can transfer documents to persons in conformity with the data protection provisions. This is the case e.g. when subjects revoke their consent (send completed revocation form to SC for archiving) or when quality reports are sent to the chief investigators.

The SC can submit a download ticket by downloading the documents.

The workflows are illustrated in Figure 3 and are outlined in this section.

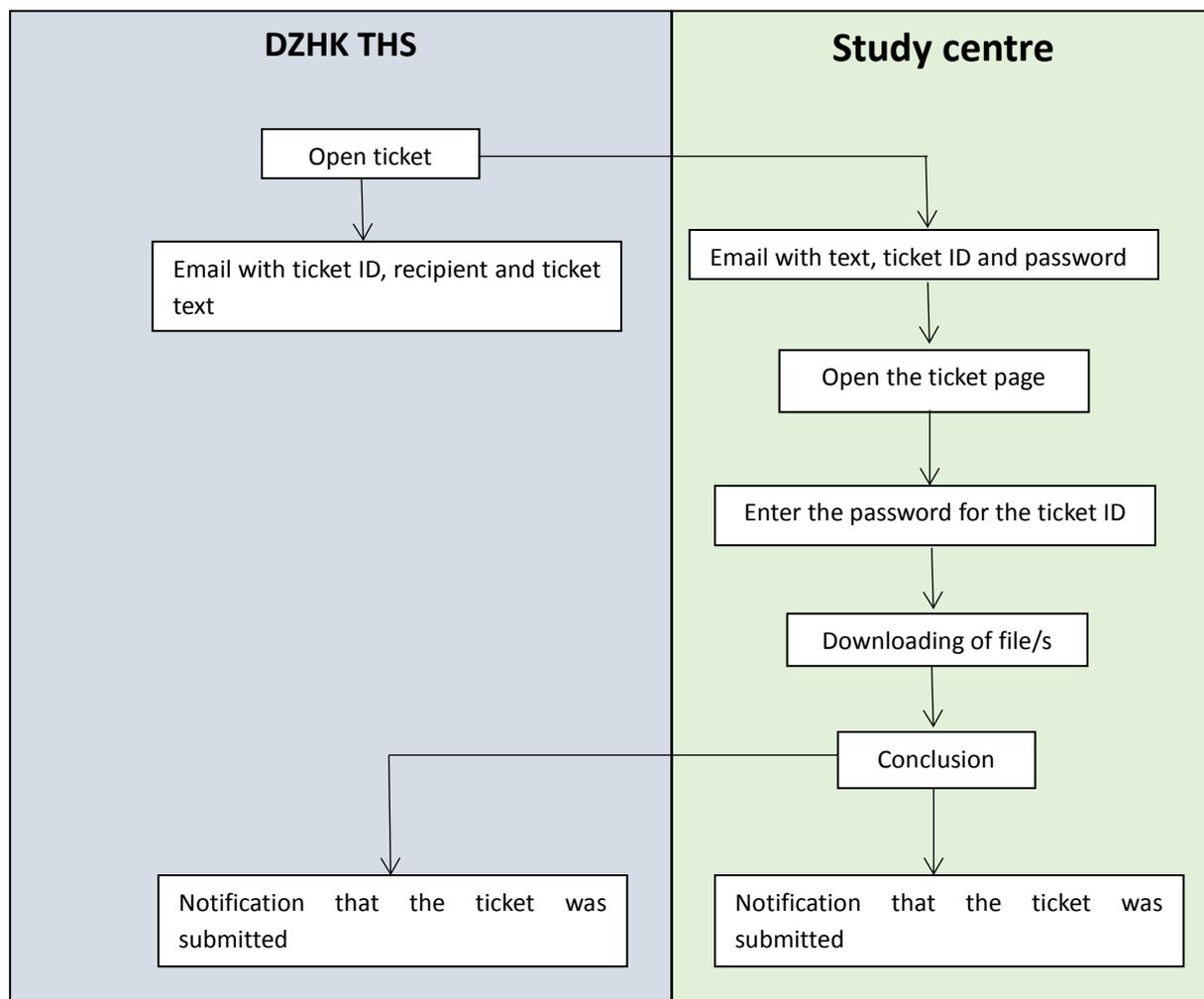


Figure 3: Flowchart for processing a download ticket

6.2.1 Submission of a download ticket by the study centre

Click on the link in the email to enter a download ticket. An example of an email is provided in annex Figure A- 1. After entering the PIN (see annex Figure A- 2) you will be forwarded to the TTP page for downloading files (see Figure 4). To display the content of the download ticket, simply click on the plus symbol in "Content of the ticket respectively e-mail". To download a file, click on "Download". End the process by clicking on "Finish".

Download file(s) from the Trusted Third Party.

Here you can download the necessary files from the Trusted Third Party needed for the process to complete.

Ticket-Number: 1636

Ticket from: Maja Mustermann

+ Content of the ticket respectively the e-mail

+ Comment

| Filename | Filesize (KB) | Action |
|-------------------------|---------------|--------|
| Beispiel für eine Datei | | |

✖ Cancel
✔ Finish

Figure 4: Page for downloading files from the TTP

The ticket **cannot** be submitted a second time. Also here the ticket is invalid by clicking on "Cancel". 28 days after a ticket is opened, the ticket expires and is no longer valid. In this case, please contact the TTP Support.

7 Responsibilities

7.1 Study centre

Can request an upload ticket by email from the Independent Trusted Third Party in the CDM of the DZHK. The SC is prompted to process the ticket and thus to upload file(s).

Furthermore, the SC can download documents provided by the TTP by means of a download ticket.

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-Vorpommern
www.landesrecht-mv.de

9 Persons involved in creating the SOP

| Name | Role | Involvement |
|------------------|----------------------|-------------|
| Katrin Leyh | Medical Data Manager | Author |
| Dana Stahl | Research Associate | Reviewer |
| Kerstin Weitmann | Research Associate | Reviewer |

10 Applicable documents

None

11 Annex

We need your support for a process in the Trusted Third Party. For more information, please see the task description below.

Please open the link below on a pc with the client certificate installed required to communicate with the Trusted Third Party.

<https://ths.dzhk.med.uni-greifswald.de:443/dzhk-ticket/html/ticket/checkTicket.xhtml?ticketId=1634>

Please insert the following PIN there: **f0076**

Task description

Dear ladies and gentlemen,

hereby I send you a request for a ticket concerning the upload of an informed consent.

Sincere regards,

Maja Musterfrau

Figure A- 1: Email to ticket recipient

process ticket

Ticket-ID *

PIN *

Figure A- 2: Page to enter the PIN

Ticket successfully redeemed.

You have redeemed the ticket successfully. The ticket can't be redeemed again.

Figure A- 3: Note that a ticket was submitted successfully

The following ticket has been processed. We are about to handle the ticket. We will contact you for any further questions.

Ticket-ID: 1635

The following files have been uploaded to the trusted third party:

- 1.pdf

Content of the ticket

Dear ladies and gentlemen,
hereby I send you a request for a ticket concerning the upload of an
informed consent.

Sincere regards,

Maja Musterfrau

Figure A- 4: Example of an email confirmation for the person submitting the ticket