



## DZHK System Verification Protocol

### Version 1.7

## Independent Trusted Third Party (TTP) of DCM

### **Introduction**

This protocol is supposed to be used for the review of the technical and content accuracy of the TTP web forms by the main study center or international study centers and, if required, to communicate necessary corrections and improvements. The web forms cannot be released (“set as productive”) for use within DZHK until verification by the main study center or international study centers has been obtained.

To allow for future use of the forms provided by DZHK’s TTP, the work station computer at the study center must comply with the most recent data protection and security provisions. The first part of this verification protocol is used to determine whether these requirements are met. The second part of the protocol is used to review:

1. whether you may use the web forms in their current form as planned
2. whether the content of the provided web forms meet your requirements

### **Preparatory work steps**

The preparatory work steps are the requirement for communication between your work station computer at the DZHK study center and the Trusted Third Party:

1. Fill in the form “[Application for Registration, Re-registration or Deregistration of a User Access for the DZHK-IT infrastructure](#)” completely and send it to the DZHK-IT infrastructure ([infrastruktur@dzhk.de](mailto:infrastruktur@dzhk.de)).
2. After the form has been processed by the Trusted Third Party, you will receive a certificate, which will ensure the authentication towards the Trusted Third Party. You will need to import this certificate once into the web browser you are using. To do that, follow the instruction “Information Sheet for Client Certificate and secuTrial” on the [DZHK Website](#).
3. Ensure that you have a username and password for the secuTrial application. Log in to the secuTrial system using the following link: <https://st03.mi.med.uni-goettingen.de/cgi-bin/WebObjects/setup-DataCapture.woa/wa/choose?customer=DZHK>

If you encounter any technical issues, or if you have any questions, please address them to your technical contact person (e.g. system administrator) or the contact address of the DZHK's Trusted Third Party.

**Contact address**

Independent Trusted Third Party (TTP) of DCM  
Phone: 03834/86-7588  
Email: [ths-dzhk-support@uni-greifswald.de](mailto:ths-dzhk-support@uni-greifswald.de)

**Details**

Please enter the following details thoroughly and completely.

**Details on the study and yourself**

	Your details
Study	
Study site (address)	
Last name	
First name	
Email	
Phone number	

**Details on the work station computer**

	Your details
Name of computer work station	
Operating system	
Browser and browser version	

Technical contact person – for technical queries;  
e.g. competent system administrator

## Review protocol

Please complete each individual review step and answer the corresponding review question with YES or NO in the column YES/NO.

The review steps are to be answered consecutively. Therefore, you must stick to the order given at all times. As soon as you need to answer a review question with “No”, stop the test and contact the Trusted Third Party.

The column “Comment” allows you to provide remarks on the individual review step.

### Part 1: Review of security requirements

Name of review step	Proceeding and review question	YES/NO	Comments on technical aspects and content
<p>Checking browser encryption</p>	<p><b>Procedure:</b> Open the following URL in the browser: <a href="https://browser-test.med.uni-greifswald.de/">https://browser-test.med.uni-greifswald.de/</a></p> <p><b>Review question:</b> Do you see a green field showing the text “Ihr Browser unterstützt TLS 1.2. Sie müssen nichts weiter tun.” (Your browser supports TLS 1.2. No further action is required.)</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
<p>Verification of the authentication</p>	<p><b>Procedure:</b> Open the following URL in the browser: <a href="https://test.ths.dzhk.med.uni-greifswald.de/dzhk/html/authenticated.xhtml">https://test.ths.dzhk.med.uni-greifswald.de/dzhk/html/authenticated.xhtml</a></p> <p><b>Review question:</b> Do you see a green field showing the text “Sie wurden erfolgreich von der Treuhandstelle authentifiziert. Sie müssen nichts weiter tun.” (You have been successfully authenticated by the Trusted Third Party. No further action is required.)</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	

**Part 2: Review of forms regarding technical aspects and content**

Name of review step	Proceeding and review question	YES/NO	Comments on technical aspects and content
Opening the application	<p><b>Procedure:</b></p> <ol style="list-style-type: none"> <li>1. Log in to the secuTrial application (test environment).</li> <li>2. Open the menu item “Neuer Patient” (New patient).</li> <li>3. Follow the first instruction by selecting your project.</li> <li>4. Follow the second instruction by selecting your study centre.</li> <li>5. Follow the third instruction by entering the current date.</li> <li>6. Confirm the entries via “Weiter” (Continue).</li> </ol> <p><b>Review question:</b> Are you being forwarded to the web form “Neuer Teilnehmer – Hinweise” (New Participant – Hints)?</p>	<input type="checkbox"/> Yes  <input type="checkbox"/> No	
Creating a new participant	<p><b>Procedure:</b></p> <ol style="list-style-type: none"> <li>7. Click the menu item “Weiter” (Continue) on page “Neuer Teilnehmer – Hinweise” (New Participant – Notes).</li> <li>8. You will be forwarded to page “Neuer Teilnehmer – Erfassung von personenidentifizierenden Daten (IDAT)” (New Participant – Acquisition of Person Identifying Data (IDAT)). Here, complete the mandatory fields with fictitious/test data.</li> <li>9. Confirm the entries via “Weiter” (Continue).</li> </ol> <p><b>Review question:</b> Are you being forwarded to the form “Neuer Teilnehmer – Erfassung des Informed Consent” (New Participant – Registration of Informed Consent)?</p>	<input type="checkbox"/> Yes  <input type="checkbox"/> No	

Name of review step	Proceeding and review question	YES/NO	Comments on technical aspects and content
Creating an Informed Consent	<p><b>Procedure:</b></p> <p>10. Select either “Yes” or “No” for all Informed Consent modules.</p> <p>11. Enter a name of your choice into the entry field “Name des aufklärenden Arztes” (Name of attended physician).</p> <p>12. Enter the current date into the entry field “Datum der Unterschrift des Arztes” (Date of physician signature).</p> <p>13. Enter the current date into the entry field “Datum der Unterschrift des Teilnehmers” (Date of participant signature).</p> <p>14. Select the field “Hiermit bestätige ich[...]” (I hereby confirm [...]).</p> <p>15. Press the button “Weiter” (Continue) (<b>alternatively:</b> “Weiter” (Continue) for studies with multiple Informed Consent forms).</p> <p><b>Review question:</b></p> <p>Are you being forwarded to the form “Neuer Teilnehmer – Scan hochladen und abschließen” (New Participant – Upload Scan and Complete)?</p> <p>(<b>alternatively:</b> another form “Neuer Teilnehmer – Erfassung des Informed Consent” (New Participant – Recording Informed Consent) for studies with multiple informed consent forms)</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	
<p><b>For studies with multiple Informed Consent forms only</b></p> <p>Recording additional Informed Consents and overview page</p>	<p><b>Procedure:</b></p> <p>1. Complete all additional Informed Consent forms similarly to the previous step.</p> <p>2. You can omit optional Informed Consent forms with the button “Überspringen” (Skip).</p> <p>3. After the last partial consent, you will be forwarded to the form “Neuer Teilnehmer – Übersicht der Informed Consents” (New Participant – Overview of Informed Consents).</p> <p>4. Press the button “Teilnehmer anlegen” (Create participant).</p> <p><b>Review question:</b></p> <p>Are you being forwarded to the form “Neuer Teilnehmer – Scan hochladen und abschließen” (New Participant – Upload scan and submit)?</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	

Name of review step	Proceeding and review question	YES/NO	Comments on technical aspects and content
Completing entries	<p><b>Procedure:</b></p> <p>5. Upload any PDF in the form “Neuer Teilnehmer – Scan hochladen und abschließen” (New Participant – Upload scan and submit).</p> <p>6. Confirm via “Teilnehmer anlegen” (Save participant).</p> <p><b>Review question:</b></p> <p>Are you being directed back to secuTrail?</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	

**Further remarks**

**Release of input masks and processes for the above-mentioned study:**

The above questions complete the technical review. Please confirm below whether the input masks and processes tested above meet your study’s content requirements.

**The input masks and processes of the Trusted Third Party to record Person Identifying Data and the Informed Consent meet the above-mentioned study’s content requirements** →  Yes  No

Place, date

Name executing person

Signature executing person