DZHK-SOP-P-06- Acquisition of participants and consents in the DZHK

(DZHK-THS_SOP_05A_EN_Acquisition of PII and IC)

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This SOP is a translation from the original German SOP and valid without signatures.

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1 INTRODUCTION

1.1 ABBREVIATION LIST

DZHK .....*Deutsches Zentrum für Herz-Kreislauf-Forschung e.V.*
IC .....*informed consent*
IDAT.....*identifying data*
SOP .....*Standard Operating Procedure*
TTP .....*Independent Trusted Third Party*
DZHK .....*Deutsches Zentrum für Herz-Kreislauf-Forschung e.V.*
IC .....*informed consent*
PII .....*personally identifiable information*
SOP .....*Standard Operating Procedure*
TTP .....*Independent Trusted Third Party*

1.2 OBJECTIVE

This Standard Operating Procedure (SOP) aims to define the processes for the collection and modification of personally identifiable information (PII) and contact details of study participants and their informed consent (IC) by the enrolling study centre.

1.3 TARGET GROUP

The SOP addresses the study staff for Deutsches Zentrum für Herz-Kreislauf-Forschung e.V. (DZHK) projects who use the Independent Trusted Third Party (TTP) as a partner ("you") in the course of their work. These can be studies as well as registries and cohorts. For simplicity, the term "study" is used.

1.4 APPLICATION AND TASKS

With the foundation of the Deutsche Zentrum für Herz-Kreislauf-Forschung e.V. (DZHK)[1], a central technical platform for the collection and documentation of study data, bio samples and image data was built for numerous clinical studies, cohorts and registries taking place at the DZHK. This should ensure the subsequent data and samples utilisation for a broad research community. In 2013, the DZHK implemented a realisation concept for informational separation of powers[2] which was previously approved by federal data protection officers and the federal government for projects of this size and

[1] https://dzhk.de/en/research/clinical-research/clinical-research-platform/ .
[2] This concept was already implemented by the NAKO health study with the support of the Federal Data Protec-

relevance. Thus, a central research platform is established in order to minimise the risk of re-identification of individual study participants. For this purpose, the DZHK research platform was set up in accordance with the TMF e.V.[3] Data Protection 2.0 guideline. Figure 1 depicts the components constituting the DZHK research platform[4]. The systems carry out the following processing procedures:

- Trusted Third Party: Management of personally identifiable information and declarations of consent including study participants withdraws, pseudonymisation.
- secuTrial®: Management of eCRFs, SAE Notifications, bio sample management for study sites which are not part of the DZHK-Clinical-Study unit.
- CentraXX (only DZHK-Clinical-Study Units): Bio sample management.
- TrialComplete: Picture and bio signal data management.
- Transfer point: Data and sample compilation for the subsequent use on the basis of a specific and by the DZHK and Access Committee approved research question[5].

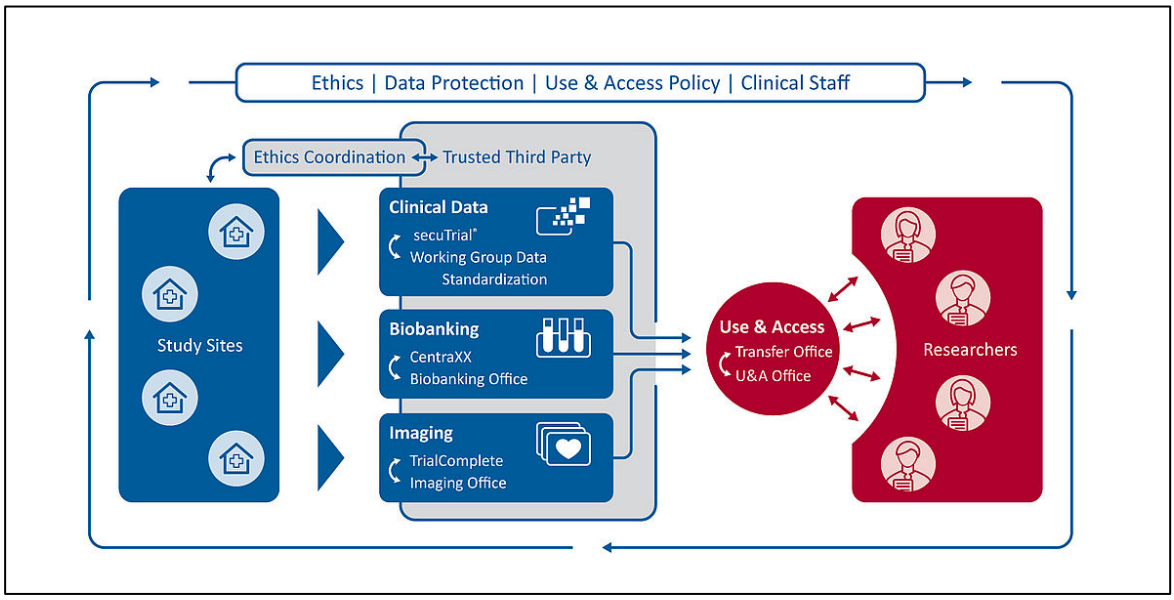


Figure 1: Structure of the DZHK´s clinical research platform

tion Commissioner.

[3] Guide in German: https://www.tmf-ev.de/sites/default/files/2023-10/tmf-schriftenreihe-band-11-leitfaden-zum-datenschutz-in-medizinischen-forschungsprojekten.pdf

[4] Video in German: https://www.youtube.com/watch?v=270VuBvzcj0

[5] https://dzhk.de/en/the-dzhk/structure-and-committees/scientific-committees/

The Trusted Third Party (TTP)[6], as part of the DZHK research platform, is located at the University Medical Centre in Greifswald and, by board decision, is independent and free from instructions in order to be able to process the study participants sensitive data. Data processing is subject to the regulations of the Mecklenburg-Western Pomerania State Hospital Act, the Mecklenburg-Western Pomerania State Data Protection Act, the Federal Data Protection Act (BDSG) and the General Data Protection Regulation (GDPR). Continuemore, the Good Clinical Practice (GCP) and, for relevant studies, the Medicines Act, the Medical Devices Law Implementation Act (formerly the Medical Devices Act) and the Clinical Trials Regulation are applied.

The processing of personally identifiable data, as well as the digital depiction of study participant´s consent, fall within the TTP´s responsibility. As is customary under GCP, all original documents remain at the study center. The TTP receives only digital copies of the IC documents. The technical, personnel, spatial, and organizational measures necessary to implement the required framework conditions are to the current state of the art. They were stipulated within a data protection concept, which was discussed with the State Commissioner for Data Protection and Freedom of Information Mecklenburg-Western Pomerania and for which a positive statement has been issued.

There are several statements from different institutions on the procedure described below, which can be provided upon request.

In a network of multi-center, partly international studies, it is of the upmost importance to document data such as personal details, biological samples or medical data correctly and based on the participants' current will within the research platform's systems. Only in this case can the data be successfully evaluated for the study and provided to researchers for subsequent use with maximum efficiency.

Continue as well as in-depth information on the DZHK clinical research platform is provided in the ethics concept[7] in the DZHK´s department for clinical research as well as in its data protection concept.

1.5 TERMINOLOGY AND DEFINITIONS

The **Trusted Third Party** (TTP) manages the patient´s consent, personal data and pseudonyms. It is the

[6] https://www.medizin.uni-greifswald.de/en/research-and-teaching/core-units/

[7] Website in German: https://service4studies.dzhk.de/studienleitungen/ethik-datenschutz/ .

only post within the clinical research platform DZHK which has knowledge of the assignment between personally identifiable information (e.g. participant names) and pseudonyms.

The **data storage** manages the system secuTrial® to capture clinical data in the form of electronical Case Report Forms (eCRFs).

The **IC-Scan** is a scanned version of the paper form of the informed consent.

IC is an abbreviation for 'Informed Consent'.

An **optional informed consent** (opt. IC, optional IC) is an auxiliary consent which can be signed additionally to the study consent e.g. consenting to the collection of DZHK-bio samples

An **optional module** requires the explicit participant´s consent or refusal as it is a fixed bloc of text within the consent form.

A **digital IC** is an electronic image of the paper consent.

Entry Date refers to the date the digital IC was gathered.

Within the TTP, **personally identifiable information** (PII) serves purpose of a person´s exact identification. This includes surnames, first names, date and place of birth as well as sex.

2 PREREQUISITES AND REQUIREMENTS

- The study site uses devises according to the administrative regulations regarding IT and information security as they are subject to the site´s update management.
- The following browser versions ensure the **minimum requirements** regarding the State Commissioner for Data Protection and Freedom of Information Mecklenburg-Western Pomerania requirements[8]:
    - Microsoft Edge Version 12, or more recent
    - Chrome Version 29, or more recent
    - Firefox Version 27, or more recent
    - Safari Version 7, or more recent
    - Opera Version 16, or more recent
- User access for secuTrial® as Study Nurse or Clinical Investigator [9]
- Importing a valid TTP client-certificate in the browser[10]
- The to be incorporated person was informed and consents the study participation
- For consenting on paper:
    - Completely filled out and signed paper consent
    - Scanner
- For consenting on a tablet:
    - The tablet must be adjusted for the incorporation of participants
    - For this, use the instructions and videos regarding this topic on the TTP´s homepage[11].
- The following websites must accessible and cleared by the study site´s IT:
    - http://st03.mi.med.uni-goettingen.de/
    - https://ths.dzhk.med.uni-greifswald.de
    - https://test.ths.dzhk.med.uni-greifswald.de
    - https://ip-ths.dzhk.med.uni-greifswald.de

[8] See information sheet to client certificate and secuTrial®: https://service4studies.dzhk.de/en/studienzentren/it-nutzerzugang/ .
[9] Application from for the DZHK´s IT-infrastructure: https://service-icm.med.uni-greifswald.de/projekte/formulare/?formid=19 .
[10] Information videos in German for installing a client certificate in different web browsers: https://service4studies.dzhk.de/studienzentren/it-nutzerzugang/ .
[11] Instructions and videos in German for consenting on a tablet: https://www.ths-greifswald.de/personal/dzhk/**Error! Hyperlink reference not valid.**.

- https://basic-ths.dzhk.med.uni-greifswald.de
- https://ip-test.ths.dzhk.med.uni-greifswald.de
- https://basic-test.ths.dzhk.med.uni-greifswald.de
- https://browser-test.med.uni-greifswald.de

3 ACQUIRING A PARTICIPANT´S PAPER CONSENT

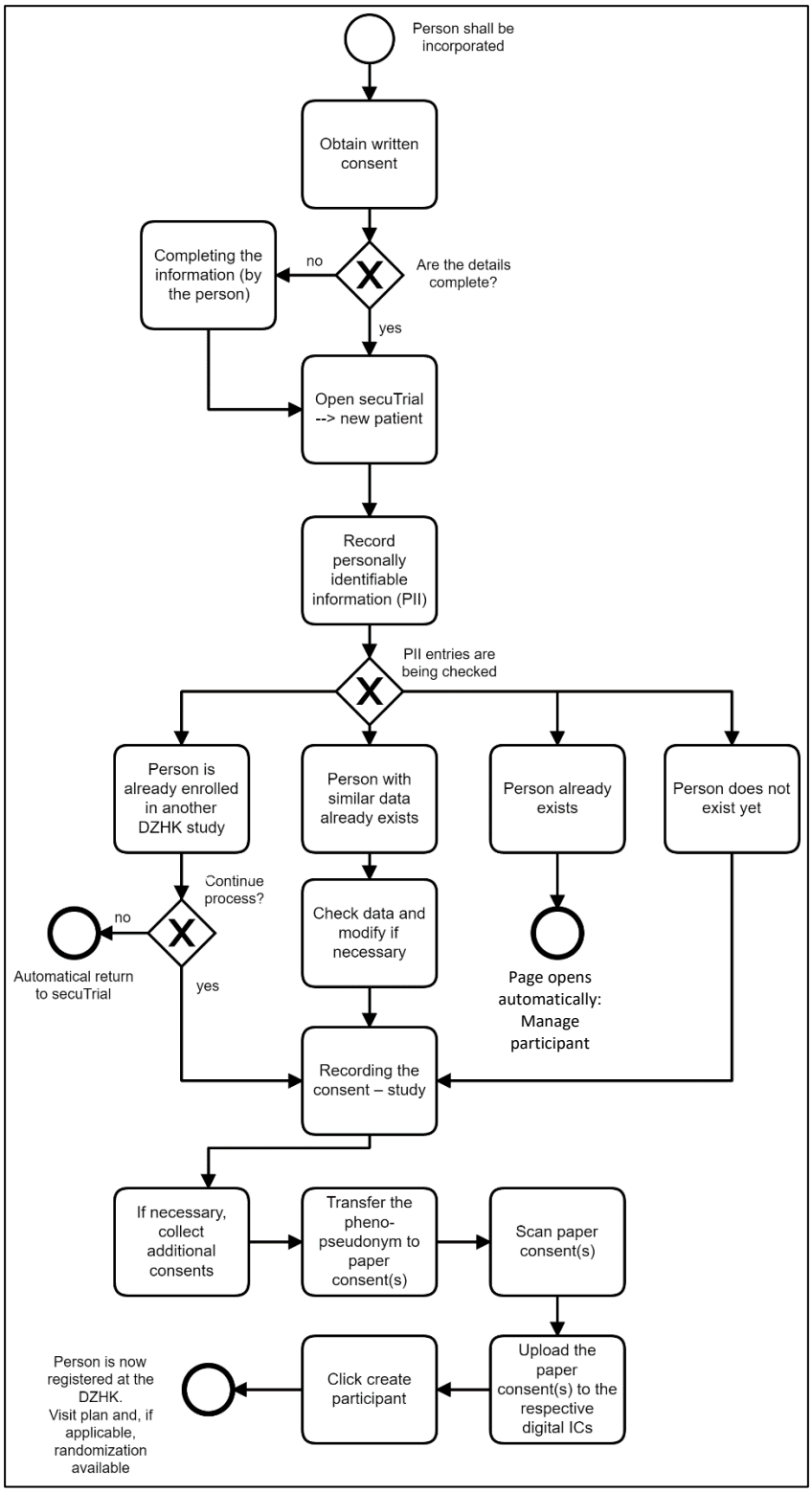


Figure 2: Procedure to incorporate a participant (paper) (simplified depiction)

3.1 Obtaining consent and registration in secuTrial®

Procedure:

1. Informing the to be incorporated person and obtaining their written consent. Ideally, they fill out the consent on paper themselves.
2. Check the consent form for correctness and completeness (all gaps are filled as well as all optional modules have a marked choice). If necessary, (let the patient) add the missing information GCP-compliant.
3. Use your user data to registrate in secuTrial´s productive system.
4. Click on *new patient* (fig. 9) on the top right button on the welcome screen.
5. Choose the project (study), the incorporating study site and state the admission date (fig. 10).
6. Click *continue*.
7. If necessary, choose your client-certificate (fig. 11)

For the registration of a new participant, you will be transferred to the TTP´s website.

3.2 Personally identifiable information (PII) acquisition

Procedure:

1. Read all depicted indications (fig. 12).
2. Click *continue*.
3. Insert all the PII and contact information of the person to be incorporated as they are captured on paper (fig. 13). Boxes marked with * are mandatory and must be filled. If the place of birth is not known, write *unknown*. An overview for the personally identifiable information is given in table 1, which can be found in the appendix.
4. Check the entry.
5. Click *continue*.

3.2.1 Checking personal data

Now, it will automatically check whether the person is already within the TTP´s database and, therefore, has already been incorporated in a DZHK study. For this, first name, surname, date and place of birth, as well as sex are compared to the existing data within the TTP. This can yield different outcomes:

1. A person with the same PII is not known to the TTP (chapter 3.2.1.1)

2. A person with similar PII is known to the TTP (chapter 3.2.1.2.)
3. A person with the same PII is already in the study for which they are to be incorporated in (chapter 3.2.1.3)
4. A person with the same PII is already incorporated in another DZHK study (chapter 3.2.1.4)

3.2.1.1 Person is not known to TTP

If there is no person matching the entered information within the TTP, then you will be transferred to capture the consent (chapter 3.3).

3.2.1.2 Person with similar information is known to TTP

If a person with similar PII already exists, the following status signal will be depicted*: There is already a person with similar information* (fig. 14).

Check the entered information. Pay attention to spelling! If you find a mistake, please, correct it.

Confirm the entry with the *continue* button. The system rechecks the data automatically. If there is no person with the entered information within the TTP, or if there is a person with similar data you will be transferred to capturing consent (chapter 3.3).

If a person with the same as the input data already exists within the TTP, then the entered PII and generated system pseudonyms will be shown (fig. 15). In this case, you can use the *finished* button to access the participant's eCRF.

3.2.1.3 Person already incorporated in study

If the results of the data comparison show that a person with the same PII is already incorporated in the desired study, then the newly inputted PII and the already existing system pseudonyms will be depicted (fig. 15).

If the person you want to incorporate into the study site was not successfully incorporated, please contact the TTP´s support team (contact data in appendix 10.1).

Use the *finished* button to access the participant's eCRF.

3.2.1.4 Person already incorporated in another study

If the results of the data comparison show a person with the same PII is already incorporated in another

DZHK study, the note, exemplified in figure 16, will be depicted. If you choose to continue the process, you will be transferred to capture consent (Chapter 3.3). If you cancel the process, you will be returned SecuTrial´s® start screen.

3.3 RECORDING CONSENT

The next step to record a person within the TTP is the transfer from the written paper consent to a digital form. If your study site offers consent sheets in a digital and analogue format, please select “On paper” when asked “How shall the consent be recorded?”.

3.3.1 Study consent

Procedure:

1. Transfer the data from the paper consent sheet to the depicted form (fig. 17).
   You will be shown your study site’s most recent version of it. If the version number does not match, it is essential to contact the TTP (contact data in appendix 10.1).
2. While transferring, pay attention to the patient’s consent in regards of optional modules (fig. 18).
3. Enter the patient´s date of signature as it is on paper (fig. 19).
4. At the end of the from, enter the name and signature date of the informing person as it is on paper (fig. 19).
5. Check the entry.
6. If everything is correct, check the conformation for content equality (fig. 20).
7. Click *continue*.

3.3.2 Optional Consent

If a study offers additional consent options next to the study-IC (e.g. DZHK bio sample collecting, sub studies), then the following pages can be analogously filled out next to study-IC (fig. 21).

If the patient did not sign the optional IC, you can use the *skip* button (at the top right) to access the next page.

3.4 UPLOADING SCAN

At this step, if you entered all consents at hand, you can check your entry and upload the scans (fig. 22).

Procedure:

1. Transfer the pheno-pseudonym (pheno_xxx) to all paper consent forms.
2. Scan the paper consent forms.
   Make sure that every scan is available as a PDF-document and is not bigger than 10 MB.
3. Upload the study´s paper consent forms to the digital study-IC.
   Click on *+ uploading Scan* and pick the document.
   If you have captured optional consents as well, please, upload each scan to the corresponding digital IC´s (e.g. scan the consents for bio sampling for the digital bio sampling IC).
4. Check your marks by clicking on *depicting scans*.
5. Click *continue*.
6. If you did not choose a document, a reminder to upload the scan will appear. If you want to continue without uploading a scan, click *yes*.

Be sure to upload the scans in a timely manner. Only person`s data with a complete and correct digital IC, including IC-scan can be used for research purposes.

3.5 COMPLETION

On this page, the previously saved PII, the generated system pseudonyms and the compiled ICs will be depicted.

With the button *compiling participant* you confirm the transfer of the system pseudonyms to the DZHK´s IT-systems.

Now you may start to enter data to secuTrial®, CentraXX or TrialComplete.

4 RECORDING PARTICIPANT´S CONSENT VIA TABLET

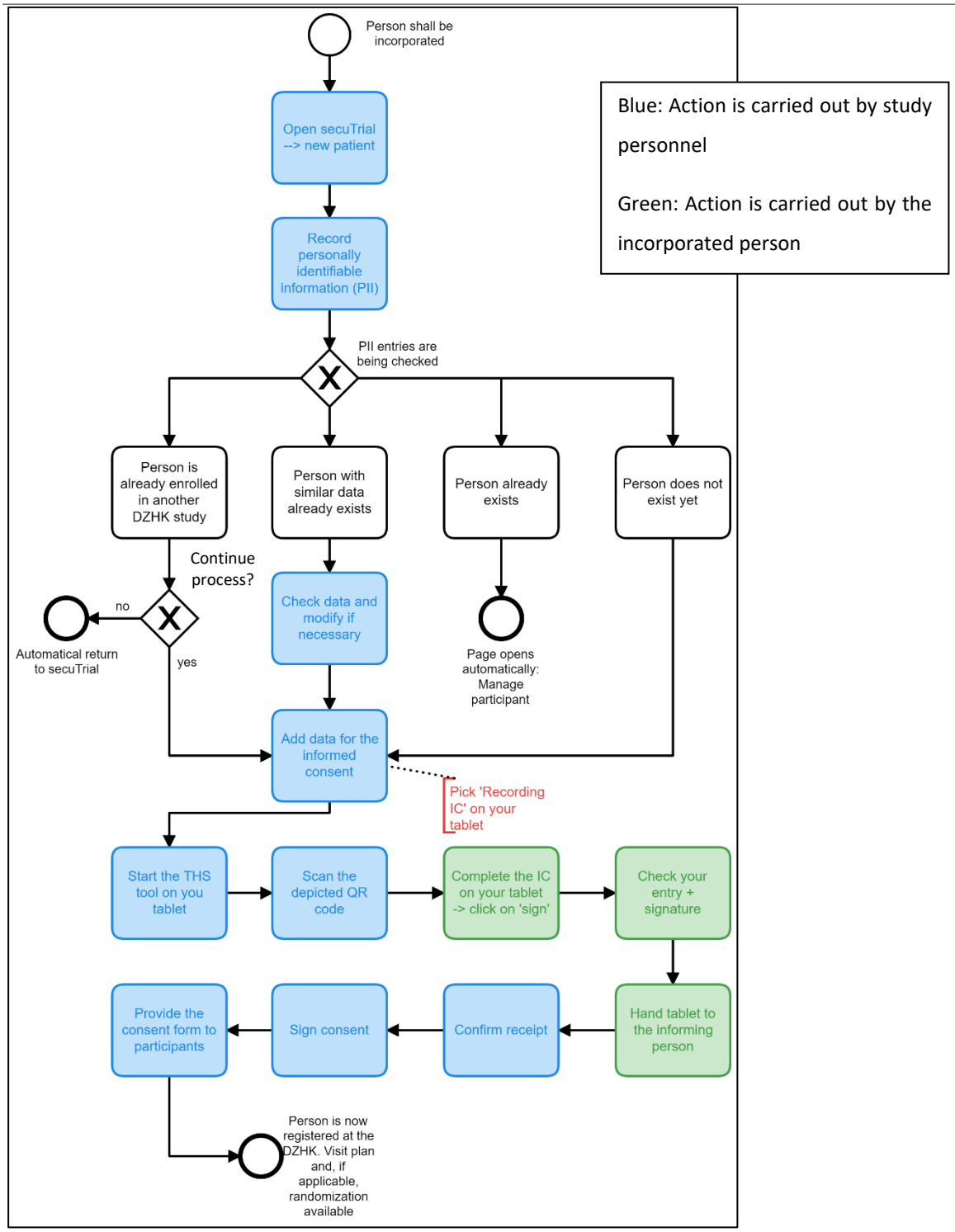


Figure 3: Procedure to incorporate a participant (tablet) (simplified depiction)

Procedure:

1. Use your user data to register in secuTrial´s® productive system.

2. Click on the button *new patient* on the welcome screen´s top right corner (fig.9).
3. Choose project (study), to be incorporated study site and date of administration (fig. 10).
4. Click *continue*.
5. If needed, choose your client-certificate (fig. 11).

For the registration of a new participant, you will be transferred to the TTP´s website.

4.1 CAPTURING PERSONALLY IDENTIFIABLE INFORMATION (PII)

Procedure:

1. Read the shown indications (fig. 12).
2. Afterwards, click *continue*.
3. Insert the PII and contact information of the person to be incorporated (fig. 13). Boxes marked with * are mandatory and must be filled. If the place of birth is not known, write *unknown*. An overview for the personally identifiable information is given in table 1 which can be found in the appendix.
4. Check your entry.
5. Click *continue*.

4.1.1 Checking personal data

The personal data check occurs analogue to **3.2.1 Checking personal data**

4.2 PREPARING TO AQUIRE CONSENT

If your study site offers consent sheets in a digital and analogue format, please select “Via tablet” when asked “How shall the consent be recorded?”.

Procedure:

1. Enter the informing person´s name and location.
2. Click *continue*.
3. Start the TTP´s application on the tablet (watch video instruction Tablet set up)
4. Scan the depicted QR code on the tablet.
5. Hand the tablet to the participant.

4.3 AQUIRING CONSENT

Procedure:

1. The participant can now fill out the study consent form.
2. Afterwards, click on *sign*.
3. The participant can check their entry and can change it if necessary.
   Ideally, they sign using a tablet pen or alternatively their finger.
4. Afterwards, please click on *send signature*.

If a study offers additional consent next to the study-IC (e.g. DZHK bio sample collecting, sub studies), then the following pages can be filled out next to study-IC (fig. 21).

If the patient does not want to sign the optional IC, they can use the *skip* button (as the top right) to access the next page.

4.4 COMPLETE AQUIRING CONSENT

Procedure:

1. Receive the tablet.
2. Confirm the tablet´s return by clicking *tablet received from participant*.
3. Ideally, the informing person signs using a tablet pen or alternatively their finger.
4. Click *send signature*.
5. Return back to SecuTrial®. There you can access and print the completed consent form, the generated pseudonyms and the PII.
6. End the process and click *compiling participant*.

With the button *compiling participant* you confirm the transfer of the system pseudonyms to the DZHK´s IT-systems. The person is now registered within the DZHK. You may start to enter data to secuTrial®, CentraXX or TrialComplete.

5 DEVIATING FROM THE STANDARD PROCEDURE – COMPILING WITHOUT PII

In consultation with the DZHK´s clinical research platform it is possible to capture participant's data without recording the PII to the DZHK. This deviation from the standard procedure has significant disadvantages and increases the workload for the study as well as the study site.

The TTP must generate pheno-pseudonyms before a person without PII can be registered. They get imported by the data handling into secuTrial® for a study site. The pseudonyms will be sent via email to the operating contact within the study site (contact person) and the local principal investigator.

In case you need further pseudonyms, please contact the TTP in a timely manner (contact data in appendix 10.1). Note that generating pseudonyms might take a couple of work days.

The following must be assured by the study site:

1. A generated pseudonym is only assigned to one person.
2. The pheno-pseudonym belongs to the participant who signed the consent form.
3. The person to be incorporated has signed the consent form.
4. There are no PII discernible on any documents which are sent to the TTP. No matter how, it is not allowed to forward PII to the TTP.
5. The paper consent form must be transferred in a digital form, before any medical data can be compiled in secuTrial®.

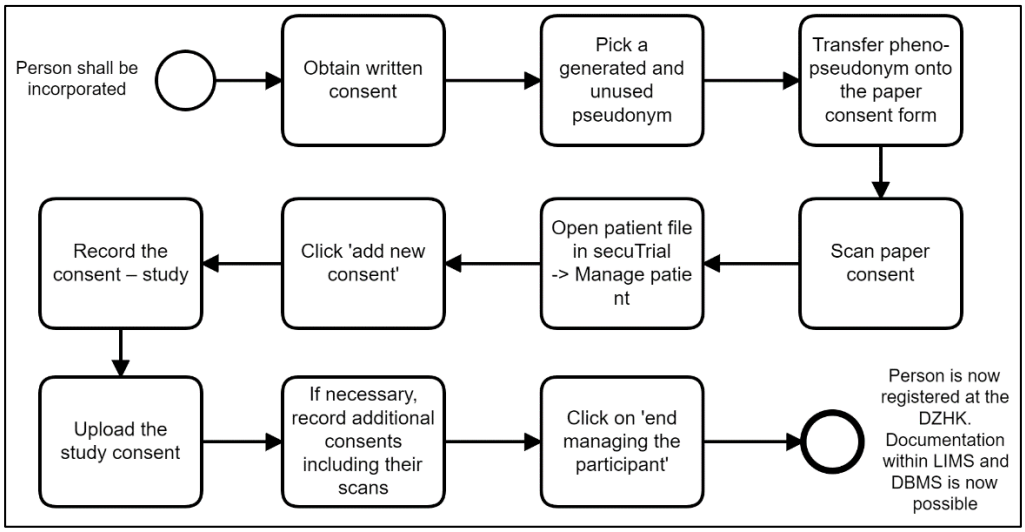


Figure 4: Procedure incorporating a participant (without PII) (simplified depiction)

5.1 PREPARING TO AQUIRE CONSENT

Procedure:

1. Informing the person to be incorporated and obtaining their consent. Ideally, they fill out the consent on paper themselves.
2. Check the consent form for correctness and completeness (all gaps are filled as well as all optional modules have a marked choice). If necessary, (let the participant) add the missing information GCP-compliant.
3. Pick a, previously by the TTP generated and unassigned, pheno-pseudonym.
4. Transfer the pheno-pseudonym onto paper consent sheet(s).
5. Scan the paper consent form.

   Attention: Neither PII nor the participant´s signature must be visible on the scan.

   Make sure that every scan is available as a PDF-document and is not bigger than 10 MB.
6. Use your user data to registrate in secuTrial®´s productive system.
7. View the pheno-pseudonym in secuTrial®.
8. Access managing participants (in the menu bar´s top: *patient…* → *edit core data and IC*)

Now you will be transferred to manage participants (fig. 23).

5.2 RECORD STUDY CONSENT

Procedure:

1. Click *+ fill out new consent form*.
2. Read the depicted indications (fig. 12).
3. Afterwards, click *continue*.
4. Chose the correct version of the paper consent. If the correct version is not selectable, contact the TTP (contact data in appendix 10.1).
5. Click *continue*.
6. Transfer the data form the paper consent sheet to the depicted form (fig. 17).
7. While transferring, pay attention to the patient's consent in regards to optional modules (fig. 18).
8. Enter the patient´s date of signature as it is on the paper consent form (fig. 19).

9. At the end of the from, enter the name and signature date of the informing person as it is on the paper consent form (fig. 19).
10. Check the entry.
11. If everything is correct, check the confirmation for equality of content (fig. 20).
12. Click *continue*.

5.3 Uploading Scan

At this step, you can check your entry and upload the scans (fig. 22).

Procedure:

1. Upload the study´s scanned paper consent form to the digital study-IC.
   Click on *+ uploading Scan* and pick the document.
   Make sure that every scan is available as a PDF-document and is not bigger than 10 MB.
2. Check your marks by clicking on *depicting scans*.
3. Click *continue*.
4. If you did not choose a document, a reminder to upload the scan will appear. **Please, upload the scan**. Only person`s data with a complete and correct digital IC including uploaded IC-scan can be used for research purposes.

Now, you may start to enter data to secuTrial®, CentraXX or TrialComplete.

5.4 Optional consent

If a study offers additional consent next to the study-IC (e.g. DZHK bio sample collecting, sub studies), then they can be captured next to study-IC.

6 CHANGING PERSONAL DATA AND CONSENT

Under *manage participants* (fig. 5), you may [1] capture new consents [2] add new documents to previously uploaded IC´s [3] change the participants contact data. Furthermore, you can view [4] the quality status of the participant´s consent as well as [5] their consent in regards of optional modules.

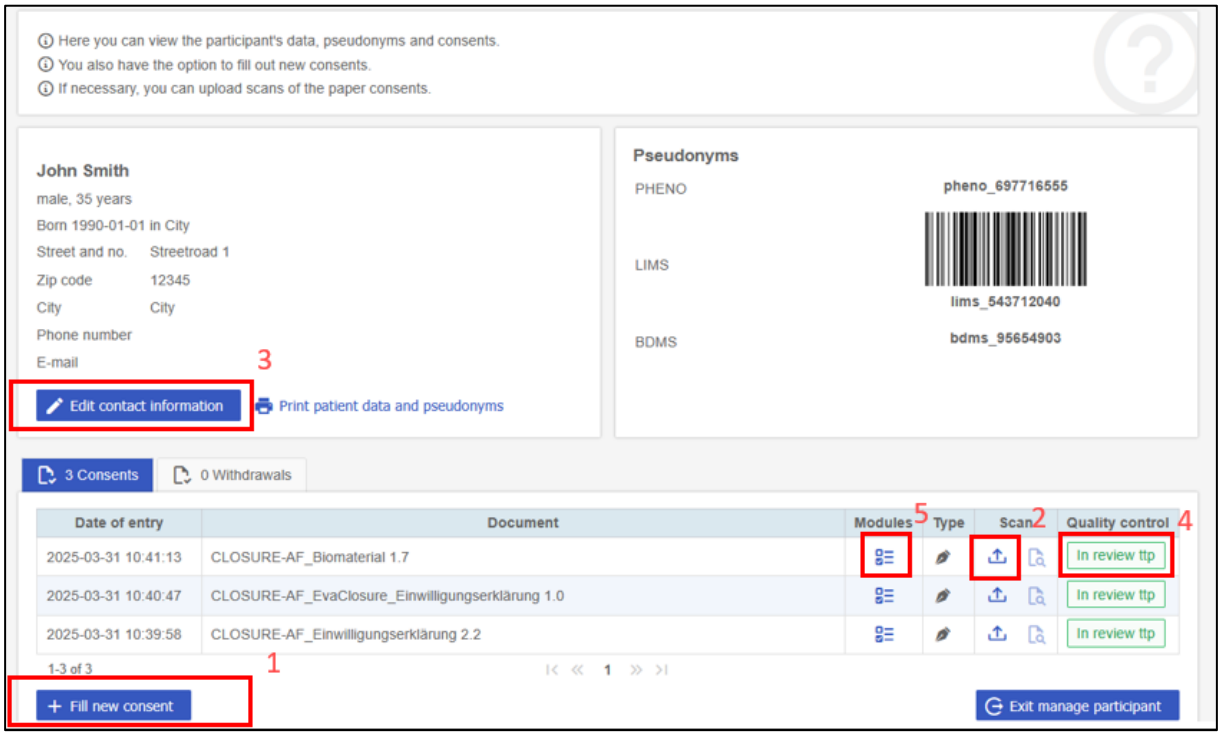


Figure 5: Manage participants website

There are two options to access *manage participants* website

a. Search the pheno-pseudonym

- Under *Select (Patient)* enter the pheno-pseudonym which can be found at the top of the menu bar (fig. 6).

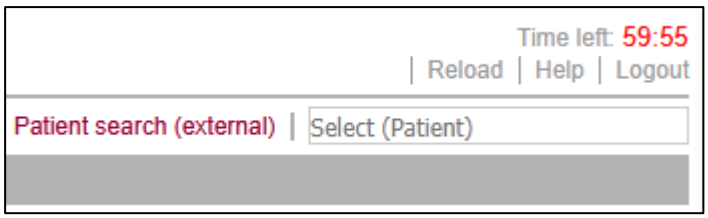


Figure 6: Searching a pheno in secuTrial®

- Press *enter.*

- At the top of the menu bar, pick: *patient…* → *edit core data and IC*.

b. Search the person

- Click *Patient search (external)* (fig. 6).
- Pick the project (study) in which you want to search.
- Choose the study site.
- Write a minimum of three letters of the first name or the surname in the search field.
- The Search starts automatically.
- If the desired person is within the results, pick them. The saved data will be shown to you (fig. 7).

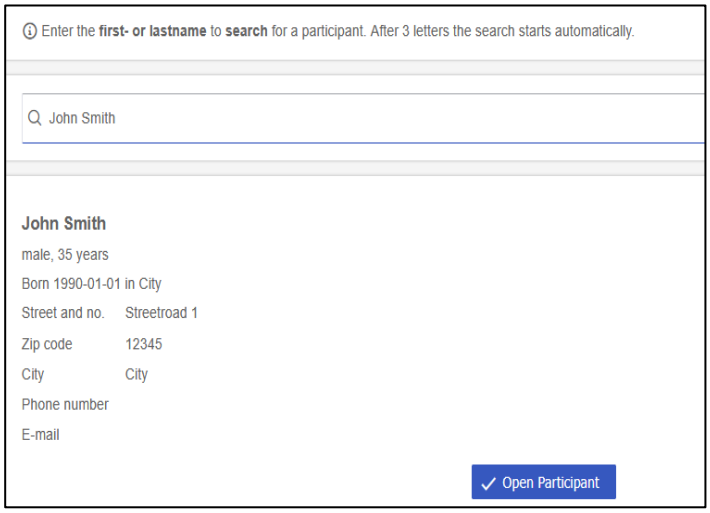


Figure 7: Searching a person in secuTrial®

- Klick *Open Particiant.*

6.1 AQUIRING NEW CONSENT

A new consent must be acquired in the following example situations:

- An error occurs during the paper consent´s implementation into the digital form.
- The participant signed a new version for the paper consent.
- The participant changed their mind in regards of some modules on the consent form and signed a new one.
- An optional consent was not recorded during the data acquisition.

Procedure:

1. If it did not happen already: scan the paper consent.
2. Access *managing participants*.
3. Click *+ new consent* form.
4. Read the depicted notes (fig. 12).
5. Afterwards, click *continue*.
6. Chose the version matching the paper consent. If this is not possible, please, contact the TTP (contact data in appendix 10.1).
7. Click *continue*.
8. Transfer the information from the paper consent to the depicted form (fig. 17).
9. During the transfer, pay attention to the patient's consent in regards of optional modules (fig. 18).
10. Enter the patient´s date of signature as it is on paper consent (fig. 19).
11. At the end of the from, enter the name and signature date of the person informing as it is on paper consent (fig. 19).
12. Check the entry.
13. If everything is correct, check the conformation for equality of content (fig. 20).
14. Click *continue*.
15. Upload the scanned paper consent(s) to the digital IC.

    Click on *+ uploading Scan* and pick the document.

    Make sure that every scan is available as a PDF-document and is not bigger than 10 MB.
16. Click *show scan* to control the upload.
17. Click *continue*.
18. If you did not choose a document, a reminder to upload the scan will appear. **Please, upload the scan.**

6.2 ADDING A DOCUMENT TO AN ESTABLISHED DIGITAL IC

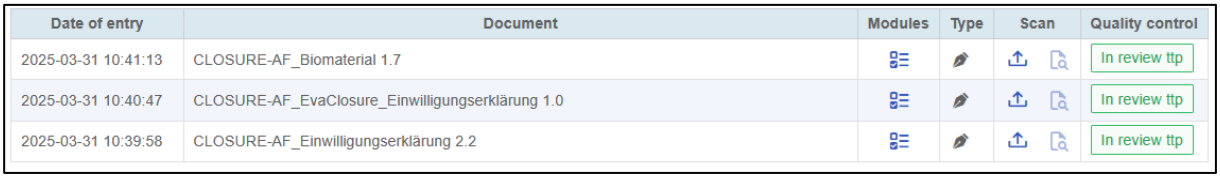
It can be necessary to add a document to an already established digital IC in the following situations:

- During application process, the scanned paper consent was not uploaded.
- The declared consent was changed or edited GCP-compliant.

- For quality control purposes the TTP asked you to fill out a note to file to clarify any uncertainties.

Prodecure:

1. If it did not already happen: scan the paper consent.
2. Access *managing participants*.
3. Click on the symbol , which you can find in the column *scan* at the digital IC in which you want to upload the document.



Date of entry	Document	Modules	Type	Scan	Quality control
2025-03-31 10:41:13	CLOSURE-AF_Biomaterial 1.7				In review ttp
2025-03-31 10:40:47	CLOSURE-AF_EvaClosure_Einwilligungserklärung 1.0				In review ttp
2025-03-31 10:39:58	CLOSURE-AF_Einwilligungserklärung 2.2				In review ttp

Figure 8: Adding a document to an established digital IC

4. Choose the desired file and confirm with OK.

The desired document is then uploaded to the chosen digital IC. You may access the files when you click on the symbol .

6.3 ADJUSTING THE CORE DATA (PII)

First name, surname, date and place of birth as well as sex are considered core data (PII) to the DZHK. These identifying markers are the TTP´s foundation for the Record Linkage (recognition of a person). Therefore, only TTP personnel is able alter this data. This can be necessary for the following cases as examples:

- Changing the participant´s name.
- An error occurred during the data transfer between the paper consent to the digital form.
- The place of birth was not known when incorporating a participant. The information is added after the study site researched it.

Procedure:

1. Email the TTP´s support (ths-dzhk@med.uni-greifswald.de)
2. Include the following details:
    - pheno-pseudonym

- correct information regarding the information which should be changed (for data protection reasons, please, use only one personally identifiable information per email)
- a brief reason.

3. When the data is adjusted, you will receive a confirmation.

6.4 EDIT CONTACT INFORMATION

The address, telephone-number and email address are considered to be contact information for the DZHK. Of course, you can alter them yourself.

Procedure:

1. Access *managing participants*.
2. Click *edit contact information*.
3. Edit the contact data to your desire, save it afterwards.

7 LITERATURE AND REFERENCES

- Information to the clinical research platform https://dzhk.de/forschung/klinische-forschung/klinische-forschungsplattform/ (last accessed: 01.07.2024).
- The DZHK´s clinical research platform https://service4studies.dzhk.de/forschungsplattform/ (last accessed: 01.07.2024).
- Data protection guide 2.0 of the TMF e.V. https://www.tmf-ev.de/sites/default/files/2023-10/tmf-schriftenreihe-band-11-leitfaden-zum-datenschutz-in-medizinischen-forschungsprojekten.pdf (last accessed: 01.07.2024)
- Explanation movie for the DZHK´s clinical research platform https://www.youtube.com/watch?v=270VuBvzcj0 (last accessed: 01.07.2024)
- DZHK Use and Access Committee https://dzhk.de/das-dzhk/struktur-und-gremien/wissenschaftliche-gremien/ (last accessed: 01.07.2024)
- Instructions and forms – 2. Installing tablet https://www.ths-greifswald.de/personal/dzhk/ (last accessed: 01.07.2024)
- Video instructions - Tablet Einrichtung Verknüpfungen (last accessed on 01.07.2024)
- Video instructions for installing the TTP´s client certificate https://www.ths-greifswald.de/personal/dzhk/ (last accessed: 01.07.2024)
- Process description and concept for data protection of the DZHK´s clinical resreach infrastructure V2.2 20.03.2023 https://service4studies.dzhk.de/studienleitungen/ethik-datenschutz/ (last accessed: 01.07.2024)
- Ethic concept for the DZHK´s clinical research area. V4.1 from 24.09.2019 https://service4studies.dzhk.de/studienleitungen/ethik-datenschutz/ (last accessed: 01.07.2024)

8 EDITING

This SOP is a translation from the original German SOP Version 2.1 from 27.01.2025. A history of all edits can be viewed in the German version.

9 PEOPLE INVOLVED

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Katrin Leyh	Author
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Dana Stahl	Content Reviewer
Pia Naumann	Content Reviewer

10 APPENDIX

10.1 CONTACT DATA TTP

Trusted Third Party of the DZHK

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17475 Greifswald

E-Mail: ths-dzhk@med.uni-greifswald.de

Telephone: +49 3834 883 1844

10.2 TABLE OF CONTENT: TABLES

10.3 FIGURES

10.4 SUPPLEMENTARY TABLE

Table 1: Notes regarding entering personally identifiable information

Marker	Mandatory field	Description	Examples
Surname	x	Enter only the participant´s most recent surname, without title and form of address. There is the separate field *birth name* in which you can write a birth or maiden name. If necessary, seperate double-barrelled names through a hyphen.	Smith Smith-Schmidt
First name	x	Enter all known and valid first names. If the participant has multiple names, enter all of them. Entering nick names or aliases is not allowed.	Michael Ann-Kathrin
Birth name		If the participant´s birth or maiden name diverges from their current surname, enter them in the field birth name. Separate double-barrelled names through a hyphen.	Bowes Bowes-Lyon
Date of birth	x	Use only numbers when entering the date of birth. The first pair states the day, the second pair states the month and the last four numbers state the year of birth. (dd.mm.yyyy)	25.11.1985
Place of birth	x	Enter the participant´s place of birth. If it is unknown, write *unknown*.	Glasgow unknown
Sex	x	Entering the participant´s sex happens through predefined selectable values.	male female other (equals *diverse*

Marker	Mandatory field	Description	Examples
			on the paper consent)
Street	x	Enter the participant´s recent and officially reported street address. Keep in mind: 1. Enter one empty space between street name and street number. 2. If a letter follows the street number, sperate them by exactly one space. 3. Enter the street number range with a hyphen or a slash.	Mainstreet 17 Street of Liberty 17 a Johnson street 17/18 Poststreet 17–18 Nelson-Mandela-Street 17
Residence	x	Enter the participants officially reported main residence.	
Postal code	x	Enter the participant´s officially reported main residence´s postcode. The postcode is only allowed to contain **five** numbers.	
Telephone number		If the study participant consents to document their telephone number, you may enter it in the according field. Write the telephone number without the international area code, including the prefix and telephone number. Only numbers are allowed as signs. You may use hyphens and spaces optionally for grouping.	030 12345-67 0123 456 789
Email address		If the study participant consents to document their email address, write their name in small letters, with exactly one @-sign.	email@example.de

10.5 SUPPLEMENTARY FIGURES

Figure 9: SecuTrial® welcome screen

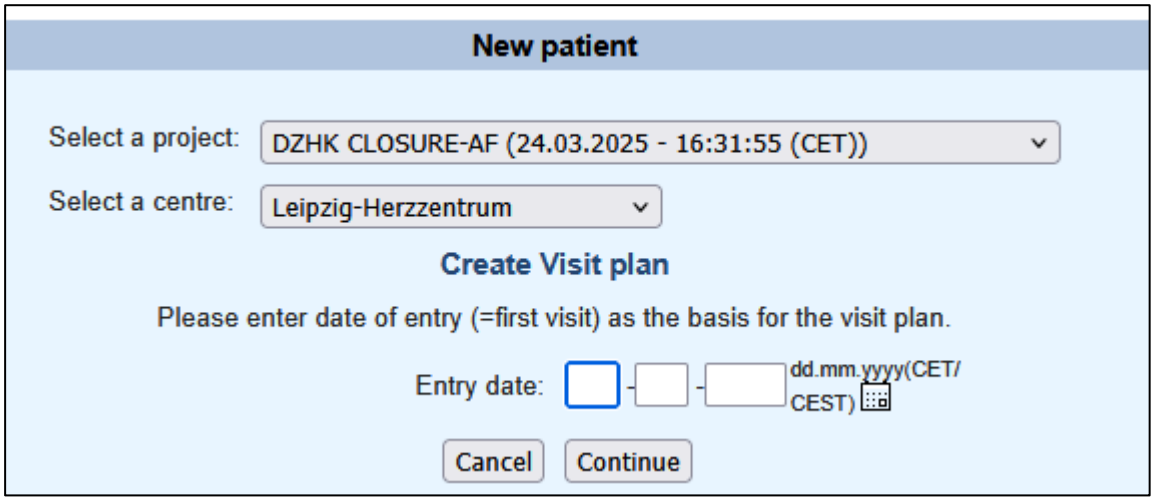

Figure 10: Choosing between project, study site and entry date

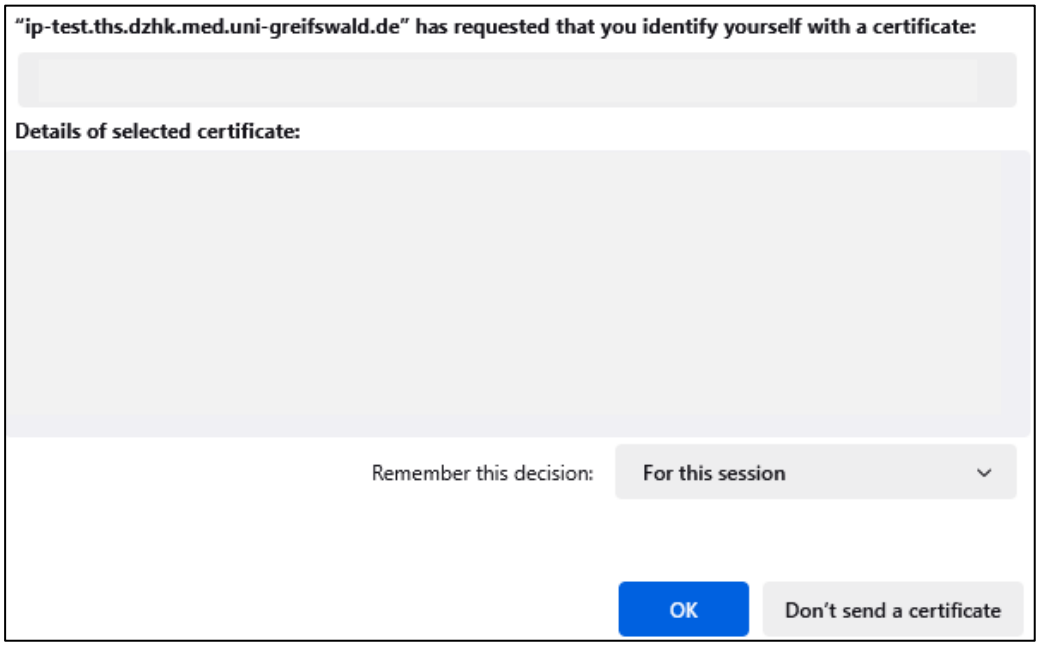

Figure 11: Choosing client certificate

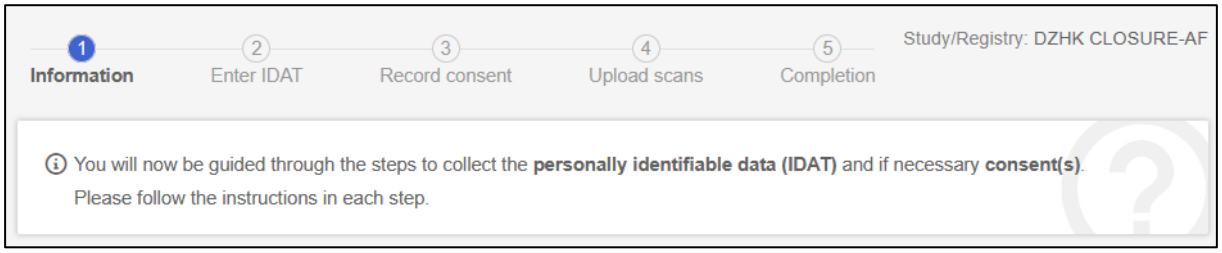

Figure 12: New Participant - note

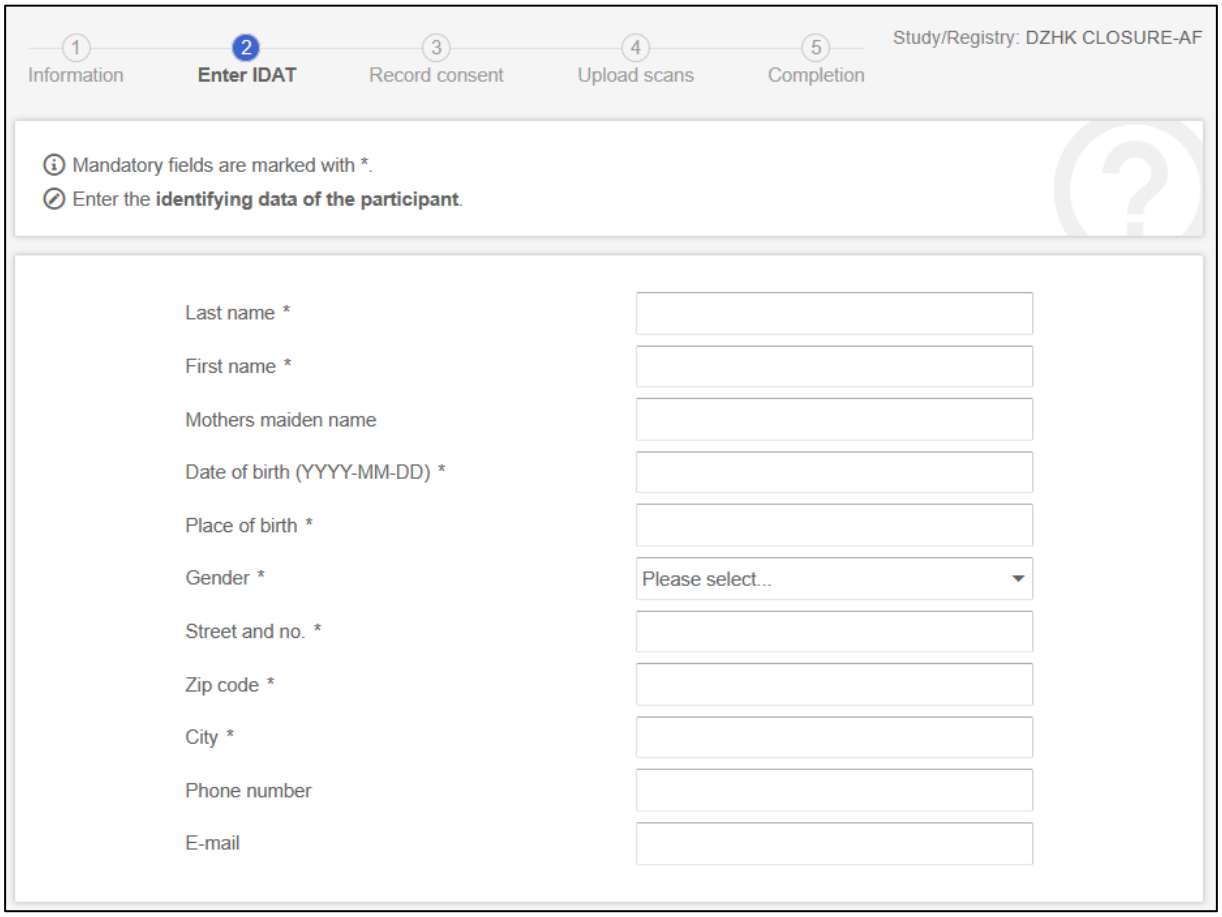

Figure 13: Input interface for personally identifiable information and contact data

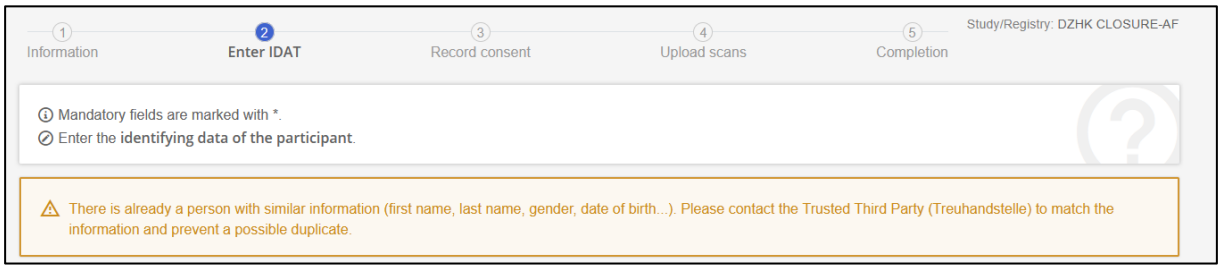

Figure 14: Note: A person with similar information already exists.

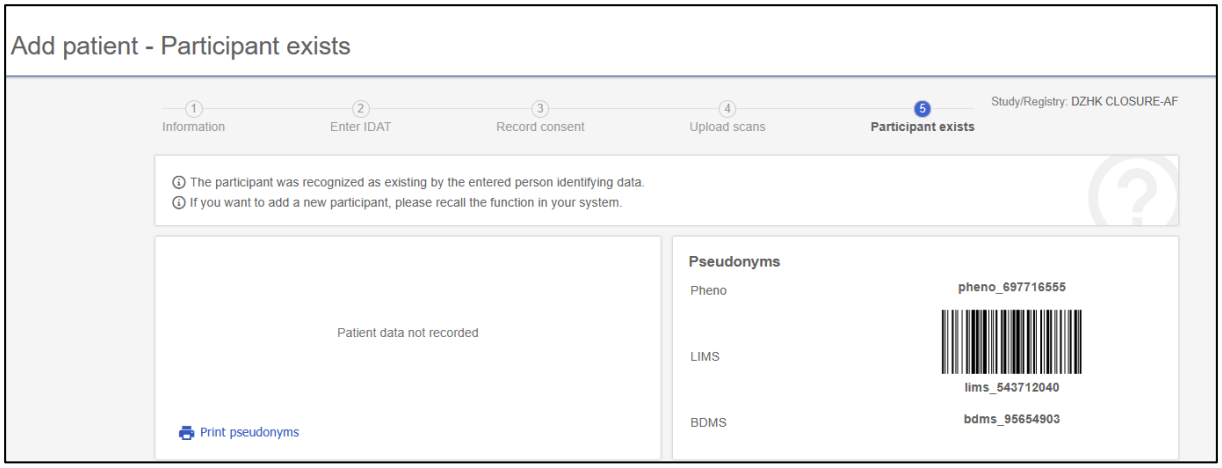

Figure 15: Depiction of system pseudonyms

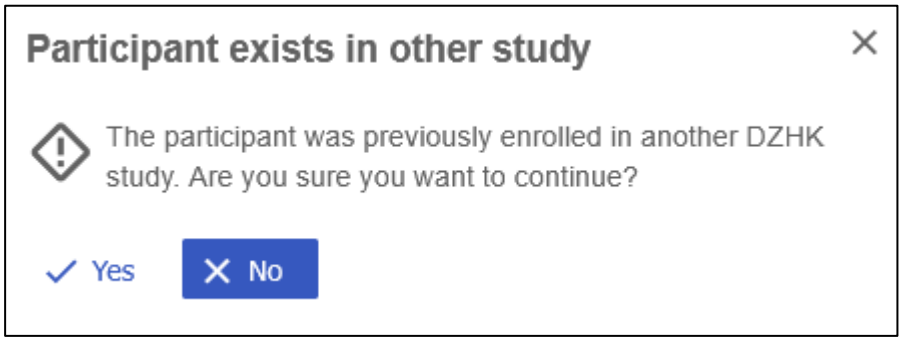

Figure 16: Note: Particpant is already incorporated in another study.

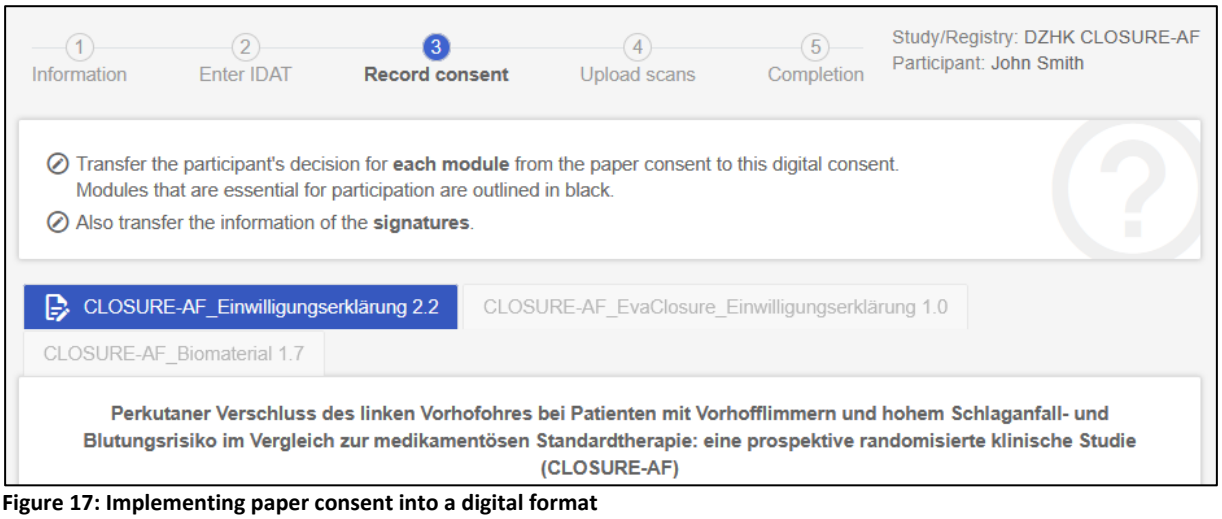

Figure 17: Implementing paper consent into a digital format

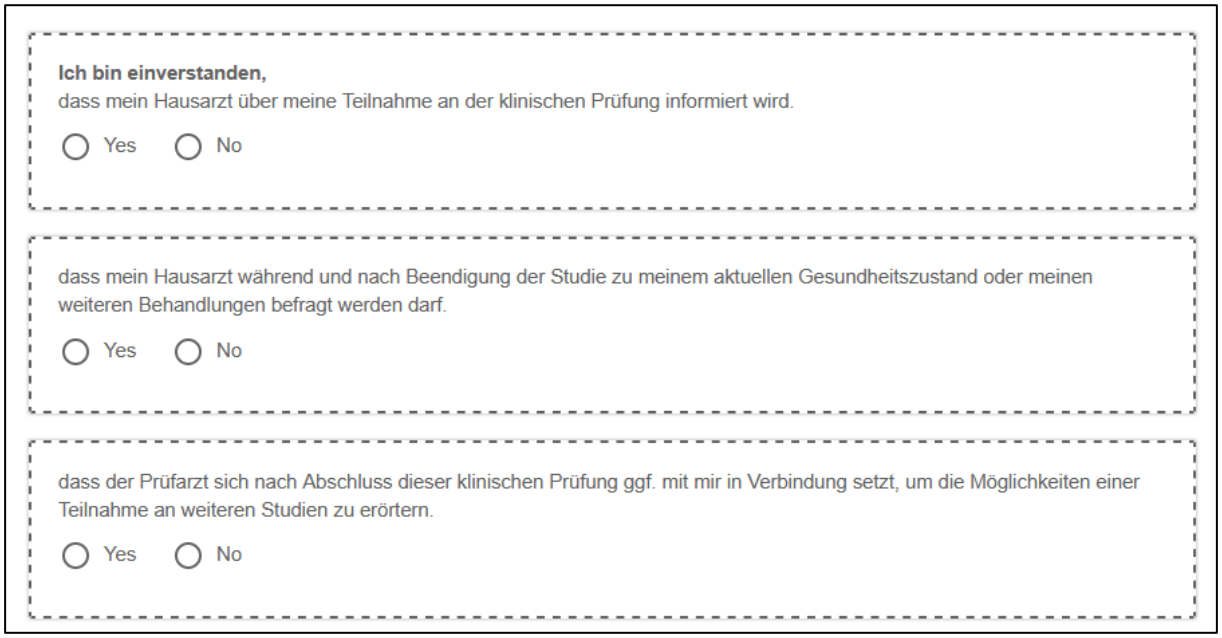

Figure 18: Patricipent gives consent regarding optional modules

Figure 19: Informing person´s and participant´s signature date

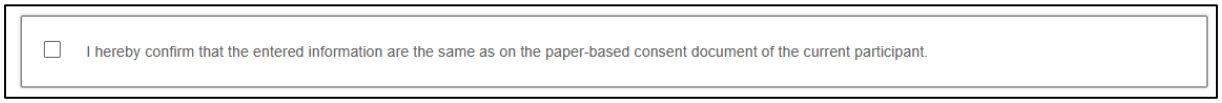

Figure 20: Confirmation of sameness between paper and digital consent

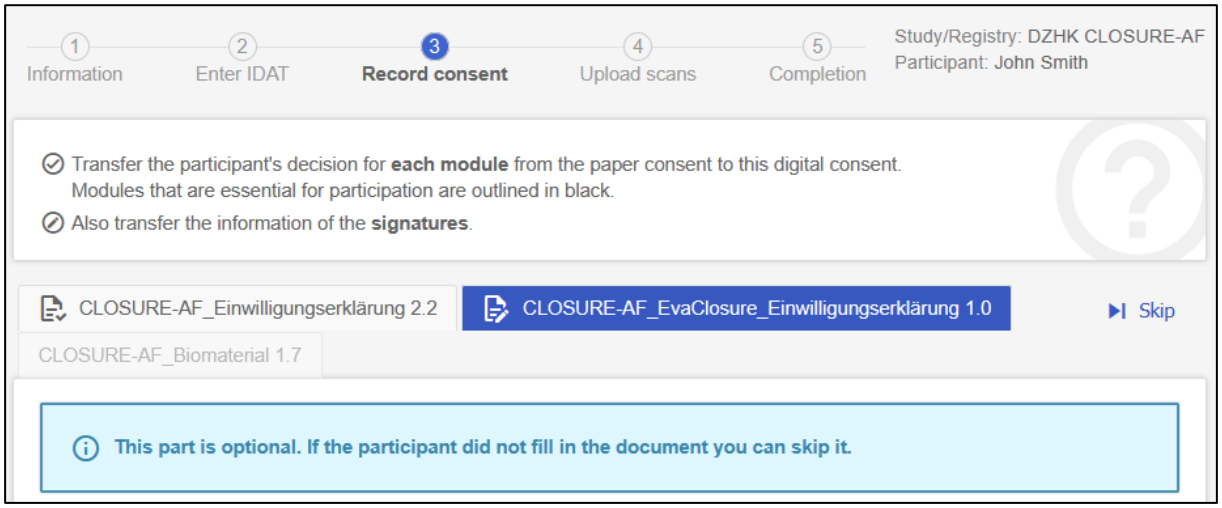

Figure 21: Acquiring optional IC´s

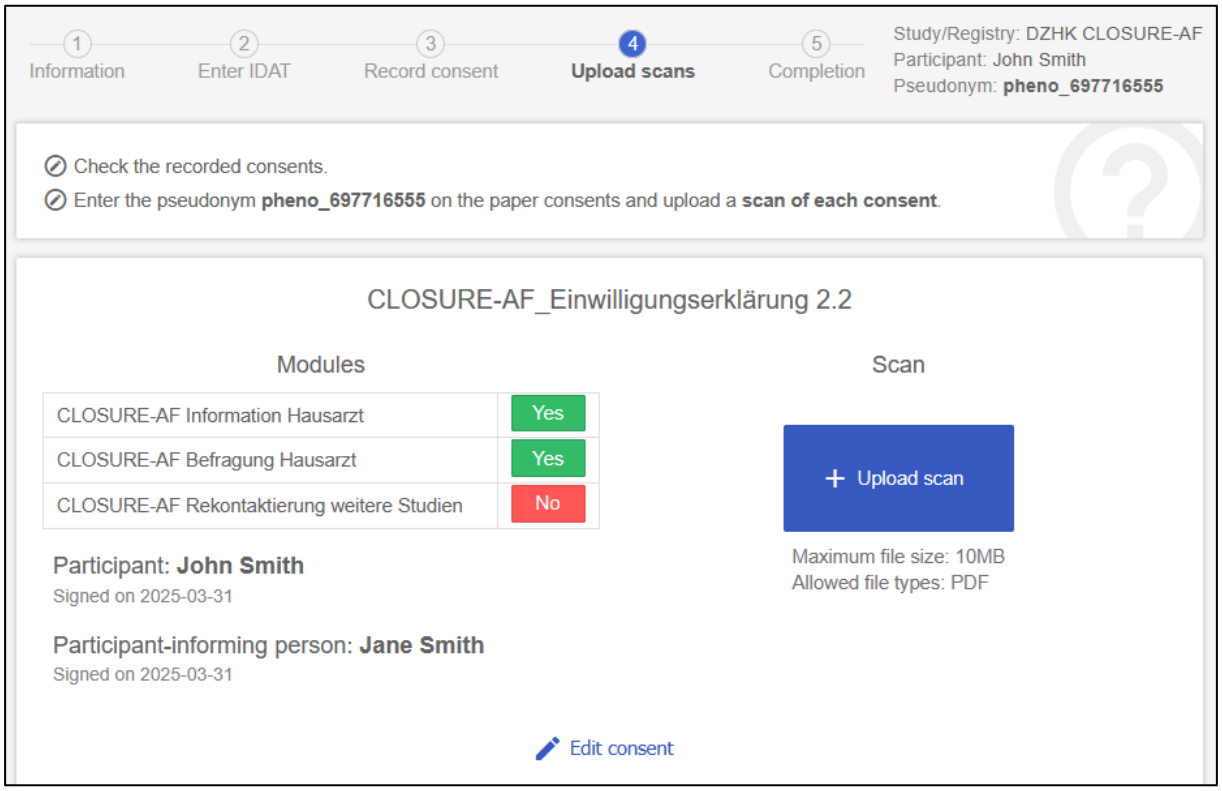

Figure 22: Uploading scans

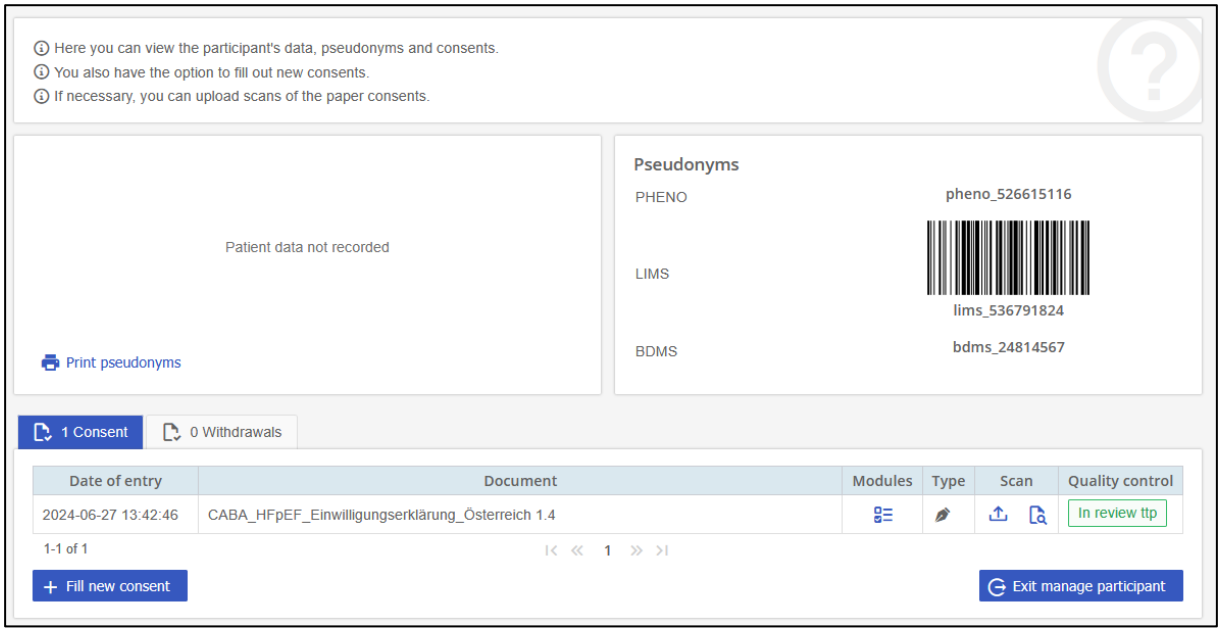

Figure 23: Managing Participants (without PII)