Information sheet on the processing of IC errors

What is the task of the Trusted Third Party of DZHK´s clinical research platform?

The Trusted Third Party (TTP) is responsible for checking the completeness and correctness of the Informed Consents (ICs). In order to do this, we carry out regular quality reviews on all Informed Consents. In addition to legal requirements[1] and guidelines[2], the concept of the IC quality review is also based on scientific research[3] and a lively exchange with people in the quality management and monitoring sector. This concept was expanded in 2021 to include a reminder process in order to have the detected errors in ICs corrected as quickly as possible. This means, that the need for a legally valid IC for the transfer of data/samples can be guaranteed very soon after the consent has been given.

How does the reminder process work?

As part of the reminder process, the responsible contact persons for the studies in the centres receive a report on the IC quality review every three weeks. In addition, the study coordination, -representatives and, if applicable, the monitors, receive study-specific overview reports with a summary of the most urgent cases to be processed in the centres. The first reminder in the event that an error has not been processed, with a request to process the discrepancy as soon as possible, is sent to the study coordination and, if applicable, the monitors, in an overview report to the 5th report on the IC quality review (1st reminder). If no quality-checked consent has been received by the 7th report on the IC quality review, the case appears in the overview report again (2nd reminder). At the same time, the transfer of data and, in the case of non-AMG/MPDG studies, the data entry is blocked in the IT systems of DZHK's clinical research platform. This step is necessary to prevent further data from being collected without the legal basis "Informed consent to the collection, storage and processing of data". If the TTP has still not received a legally valid IC-Scan up to the 9th report on the IC quality review, the TTP will take various measures based on the existing errors. You can see an example timeline of the reminder process in Figure 1.

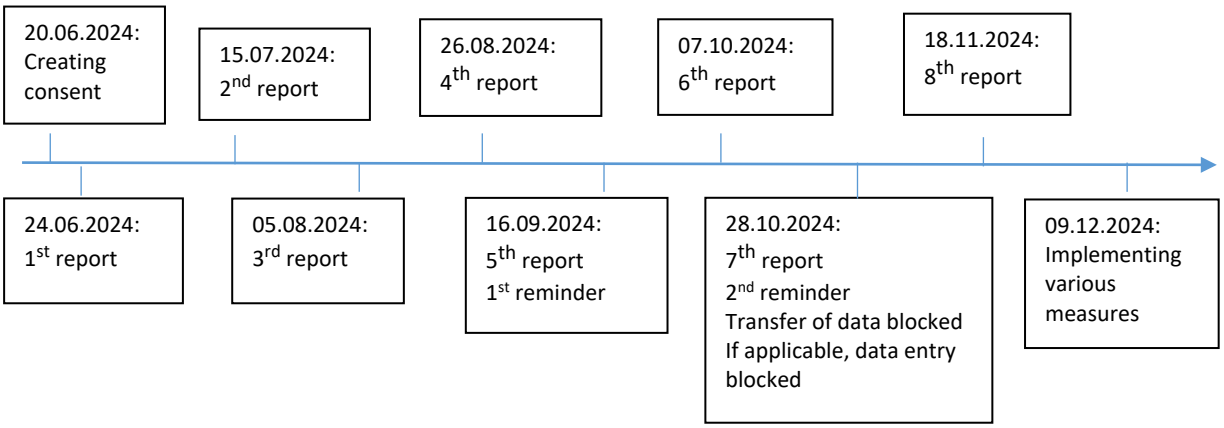


Figure 1- Example timeline of the reminder process

[1] u.a. ICH E6/GCP-Leitlinie Abschnitt 4.8.10 und § 40 Absatz 1 AMG und ICH E6/GCP-Leitlinie Punkt 8.3.12

[2] Datenqualität in der medizinischen Forschung https://www.tmf-ev.de/unsere-arbeit/produkte/datenqualitaet-in-der-medizinischen-forschung

[3] Data privacy management and data quality monitoring in the German Centre for Cardiovascular Research's multicentre TranslatiOnal Registry for CardiomyopatHies (DZHK-TORCH) https://onlinelibrary.wiley.com/doi/10.1002/ehf2.12168

What is the report on the IC quality review?

The report on the IC quality review are specific reports, which represent the results of the IC quality review, in which the corresponding consents of the participants, such as the Informed Consent for a study or Informed Consent for biosamples, are carefully checked for correctness. Besides the pheno pseudonym and the date of creation this report contains a detailed list of the discrepancies identified in the uploaded and checked Informed Consents (ICs) as part of the IC quality review process. These discrepancies require correction by the centre. Detailed instructions for processing the IC errors are attached to this document (see *Instructions to process IC errors*). The task of the receiver of the reports on the IC quality review is to process the discrepancies in accordance with the action descriptions. This ensures that the TTP is presented a legally valid IC.

How to work GCP (Good Clinical Practice) compliant?

A **GCP-compliant correction** should be conducted as follows:

- Delete wrong value. Make sure that the original font is still legible.
- Insert correct value.
- Add date of change.
- Add abbreviation of the study site employee (resp. signature of the participant in the case of changes to optional modules and the signature date of the study participants).

Recommendation of TTP: Send an updated copy to the participant.

Attention: Changes to optional modules and the signature date of the study participants should be done GCP-compliant, if possible, by the participants themselves.

In case you have any questions please contact us:

- phone: +49 3834/86-8656
- E-Mail: ths-dzhk@med.uni-greifswald.de

Instructions to process IC errors

Note: discrepancy refers to the comparison between electronic data and the data on the scan of the paper consent form.

Action description

Description 1: study centre - complete information

Application for errors:

- participant´s name is missing
- participant´s name is partially missing
- participant´s date of birth is missing
- participant´s date of birth is partially missing
- pheno-pseudonym is missing
- name of the informing person is missing
- name of the informing person is partially missing
- signature date of the informing person is missing
- signature of the informing person is missing
- name of participant´s representative is missing
- name of participant´s representative is partially missing

Processing:

- Choose the participant´s respective paper consent.
- Complete necessary information GCP-conform
- Scan the corrected IC.
- Upload the corrected consent (see **Upload document to an existing digital IC**).

Description 2: study centre - research and s.o.s. correct information

Application for errors:

- discrepancy: participant´s name
- discrepancy: participant´s date of birth
- discrepancy: participant´s sex
- discrepancy: participant´s place of birth
- participant´s name is not plausible

- participant´s date of birth not plausible
- discrepancy: pheno-pseudonym

Processing:

- Research using the documents available to you.
  a) Research outcome: Information on the scanned IC is correct.
     - Send an e-mail to TTP with the relevant pheno-pseudonym and the correct information on the IC scan.
       e.g. The information regarding the first name is correct for the pheno_123456789.
     - See also: **Altering the personally identifiable data (IDAT)**.

  b) Research outcome: Information on the scanned IC is wrong.
     - Choose the participant´s respective paper consent.
     - Correct necessary information GCP-conform.
     - Scan the corrected Informed Consent.
     - Upload corrected Informed Consent (see: **Upload document to an existing digital IC**).

  c) Research outcome: The information which is seen on the IC-scan and which is saved at the TTP, is wrong.
     - Continue as described in a) and b).

Description 3: study centre - correct information

Application for errors:

- participant´s name is not legible
- participant´s date of birth is not legible
- participant´s place of birth is not legible
- pheno-pseudonym is not legible
- name of the informing person is not legible

Processing:

- Choose the participant´s respective paper consent.
- Correct necessary information GCP-conform.
- Scan corrected Informed Consent.
- Upload the corrected Informed Consent (see: **Upload document to an existing digital IC**).

Description 4: study centre - research and s.o.s. correct information and s.o.s. record a new digital IC

Application for errors:

- discrepancy: name of the informing person
- discrepancy: signature date of the informing person

Processing:

- Research using the documents available to you.
  a) Research outcome: Information on the scanned IC is correct.
    - Record a new digital IC (see: **Record a new digital IC**).
    - Ensure that all information match exactly.
  b) Research outcome: Information on the scanned IC is wrong.
    - Choose the participant´s respective paper consent.
    - Correct necessary information GCP-conform.
    - Scan the corrected Informed Consent.
    - Upload corrected Informed Consent (see: **Upload document to an existing digital IC**).
  c) Research outcome: The information which is seen on the IC-scan and which is saved at the TTP, is wrong.
    - Choose the participant´s respective paper consent.
    - Correct necessary information GCP-conform.
    - Scan the corrected Informed Consent.
    - Upload corrected Informed Consent (see: **Record a new digital IC**).
    - Ensure that all information match exactly.

Description 5: study centre - correct information and s.o.s. recording a new digital IC

Application for errors:

- signature date of the informing person ambiguous

Processing:

- Choose the participant´s respective paper consent.
- Correct necessary information GCP-conform.
- Scan the corrected Informed Consent.
- Compare the information on the scanned IC to the digital IC.
  a) Research outcome: data is identical.

- Upload corrected Informed Consent (see: **Upload document to an existing digital IC**).

b) Research outcome: information is divergent.

- Record a new digital IC (see: **Record a new digital IC**).
- Ensure that all information match exactly.

Description 6: study centre - record new digital IC

Application for errors:

- discrepancy: IC version
- digital IC is missing
- discrepancy: optional module
- discrepancy: participant´s signature date
- discrepancy: signature date of participant´s representative

Processing:

- Record a new digital IC (see **Record a new digital IC**).
- Ensure that all information, versions and kind of IC match exactly.

Description 7: study centre - upload Informed Consent

Application for errors:

- IC scan is missing
- IC scan is partially missing
- discrepancy: kind of IC (e.g. digital IC = study IC, IC scan = biomaterial IC)

Processing:

- Choose the participant´s respective paper consent.
- Scan Informed Consent.
- Upload Informed Consent (see **Upload document to an existing digital IC**).

Description 8: study centre - fill out IC annotation

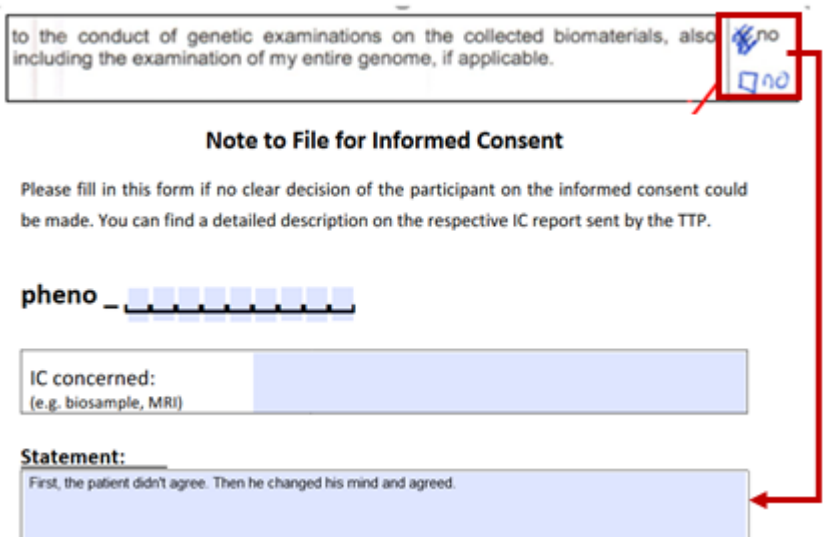
Application for errors (e.g.):

- correction is not GCP-conform
- Issues require a detailed explanation

  Note: When the instruction “Complete IC note” is given, the TTP will specify the corresponding error in the error description in the IC review reports.

Processing:

- Describe the issue in more detail on the Note to Informed Consent.
- Example:



- Scan the complete and signed IC note.
- Upload Document (see **Upload document to an existing digital IC**).

Description 9: participant - complete or correct information

Application for error:

- information regarding optional modules is missing
- information regarding optional modules ambiguous
- participant´s signature date is missing
- participant´s signature date ambiguous
- participant´s signature is missing

Processing:

- Have the participant complete or correct their information GCP-conform.
- Scan the corrected version.
- Compare the information of the corrected IC scan to the digital IC.
  a) Research outcome: Information is identical, or only the signature was missing.
     - Upload the corrected Informed Consent (see **Upload document to an existing digital IC**).
  b) Research outcome: information is divergent.
     - Record a new digital IC (see **Record a new digital IC**).

- Ensure that all information match exactly.

Description 10: participant´s representative - complete or correct information

Application for errors:

- information regarding optional modules is missing
- information regarding optional modules ambiguous
- signature date of the participant´s representative is missing
- signature date of the participant´s representative not ambiguous
- signature of the participant´s representation is missing

Processing:

- Have the participant´s representation complete or correct the information GCP-conform.
- Scan corrected Informed Consent.
- Compare the information on the corrected IC scan to the digital IC.
  a) Research outcome: Information is identical, or only the signature was missing.
     - Upload corrected Informed Consent (see **Upload document to an existing digital IC**).
  b) Research outcome: Information is divergent.
     - Record a new digital IC (see **Record a new digital IC**).
     - Ensure that all information match exactly.

Description 11: study centre - complete information

Application for errors:

- signature of the participant´s representation is missing

Processing:

- Print digital IC.
- Complete necessary information GCP-conform.
- Scan corrected Informed Consent.
- Upload corrected Informed Consent (see **Upload document to an existing digital IC**).

Description 12: study centre - research and s.o.s. correct information

Application for errors:

- participant´s name is not plausible
- participant´s date of birth is not plausible

Processing:

- Research using the documents available to you.
  a) Research outcome: Information on the scanned IC is correct.
     - Send an e-mail to TTP with the relevant pheno-pseudonym and the correct information on the IC scan.

       e.g. The information regarding the first name is correct for the pheno_123456789.
     - See also: **Altering the personally identifiable data (IDAT)**
  b) Research outcome: Information on the scanned IC is wrong.
     - Print digital IC.
     - Correct necessary information GCP-conform.
     - Scan the corrected Informed Consent.
     - Upload the corrected Informed Consent (see: **Upload document to an existing digital IC**).
  c) Research outcome: The information which is seen on the IC-scan and which is saved at the THS, is wrong.
     - Continue as described in a) and b).

Description 13: participant – complete information

Application for errors:

- participant´s signature is missing

Processing:

- Print digital IC.
- Have the participant complete the respective information GCP-conform.
- Scan the corrected Informed Consent.
- Upload the corrected Informed Consent (see **Upload document to an existing digital IC**).

Description 14: representation of a participant – complete information

Application for errors:

- signature of the participant´s representative is missing

Processing:

- Print digital IC.
- Have the participant´s representation complete the respective information GCP-conform.
- Scan the corrected Informed Consent.
- Upload the corrected Informed Consent (see **Upload document to an existing digital IC**)

Record a new digital IC

Procedure:

- If you have not done so yet: scan the paper consent (pdf).
- Navigate to the site *manage participant*.
- Click on *+ fill out new consent*.
- Read the depicted notes.
- Afterwards, click on *continue*.
- Please select the correct version of the paper consent. If the version number is not selectable, contact the TTP (ths-dzhk@med.uni-greifswald.de).
- Click on *continue*.
- Transfer the information from the paper consent to the depicted form.
- Pay close attention to the participant's information regarding optional modules during the data transfer.
- Enter the participant´s signature date as is on paper.
- At the end of the form, enter the name of the informing person as well as their signature date as is on paper.
- Check your entries.
- If everything is correct, mark *confirmation of sameness*.
- Click on *continue*.
- Upload the scanned paper consent under digital consent.
- For this, click on *+ Upload scan* and then choose the corresponding document.
  Make sure, that every scan is in a pdf document and not larger than 10 MB.
- Check your choice by clicking *depict scan*.
- Click on *continue*.
- If you did not select a document, you will receive a reminder to upload the scan**. Please upload the scan.**

Upload document to an existing digital IC

Procedure:

- If you have not done so yet: scan the paper consent (pdf).
- Navigate to the site *manage participant*.
- Click on *+ fill out new consent*.

- On the digital IC, for which you want to upload a document, click on the sign in the column *Scan*.

Figure 1: Upload a document to an already existing digital IC

- Select the desired document and confirm with *OK*.

The desires document was uploaded to the selected digital IC. Now you may access the data using the symbol.

Altering the personally identifiable data (IDAT)

The DZHK study name, first name, date of birth and date of birthplace, as well as sex are considered personally identifiable information. Those build the foundation for record linkage (reidentification of a person) within the TTP. For this reason, the TTP personnel can change the data.

Procedure:

- Write an e-mail to the TTP´s support team (ths-dzhk@med.uni-greifswald.de)
- Enter the following:
  - pheno-pseudonym
  - only the correct specification of the characteristics to be changed (for data protection reasons, please enter only one personally identifiable information per e-mail)
  - a brief reasoning.
- After the change, you will receive a confirmation.