DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

Independent
Trusted Third Party
UNIVERSITY MEDICINE GREIFSWALD

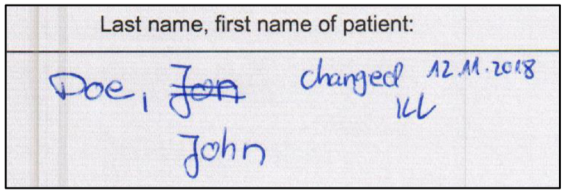
IC-verification reports are the result of context-specific checks, in which for each DZHK study the respective consent forms (study and biomaterial consent) of each participant are audited. These reports contain deviations from the target state of the uploaded and checked consent forms. For example, deviations could be missing signatures on the IC or an incompletely uploaded IC.

What do you have to do?

- retrieve the consent of the respective participant
- if applicable, edit the consent in compliance with Good Clinical Practice (GCP)

How to edit ICs in compliance with GCP?

- cross out the wrong value
- insert the right value
- document the date of change
- document the abbreviation of the study staff's name



Changes to optional modules, or the date of signature of the study participant require a confirmatory signature of the participant!

The TTP recommends: Send an updated IC-copy to the participant.

Appendix

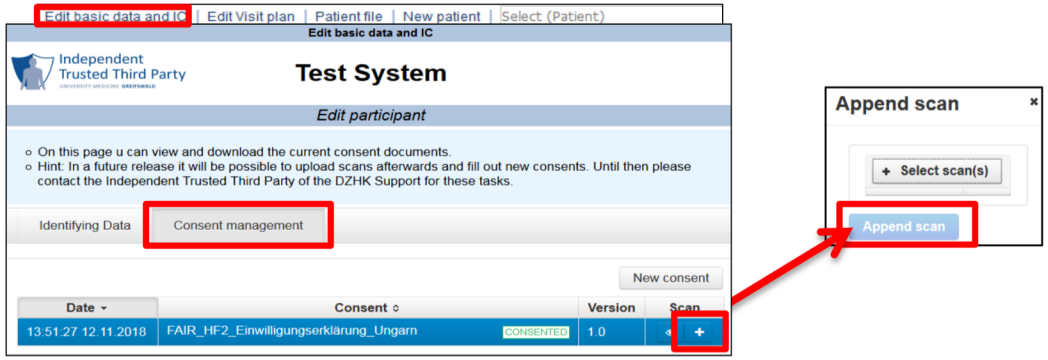
What happens after correcting an IC?

Case 1: Information regarding person-identifying data on the IC-scan are correct (no correction necessary):

- Please send an e-mail to the TTP including the relevant pheno-PSN and the corresponding information that the IC-scan is indeed correct and no changes are necessary (e.g. the first name of the participant as stated on the IC-scan is correct for pheno_123456789).

Case 2: Information regarding person-identifying data on the IC-scan is incorrect or missing:

- Scan the corrected consent.
- Search for the corresponding pheno-pseudonym in secuTrial.
- Upload the corrected IC-scan using the secuTrial-tab "Edit basic data and IC" (see SOP "DZHK-SOP-TTP-01 Acquisition-IDAT-Informed Consent").



Case 3: Information regarding optional modules on the IC is not unambiguous:

- Please explain what is meant in more detail on the file note to informed consent.
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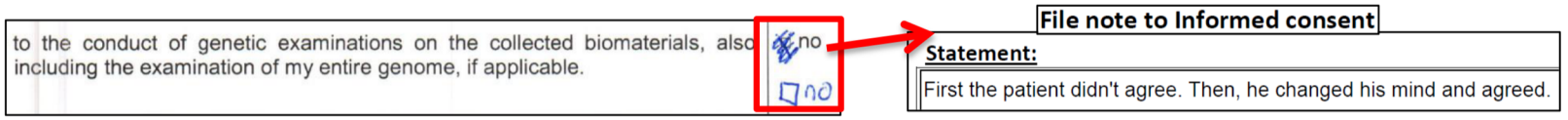
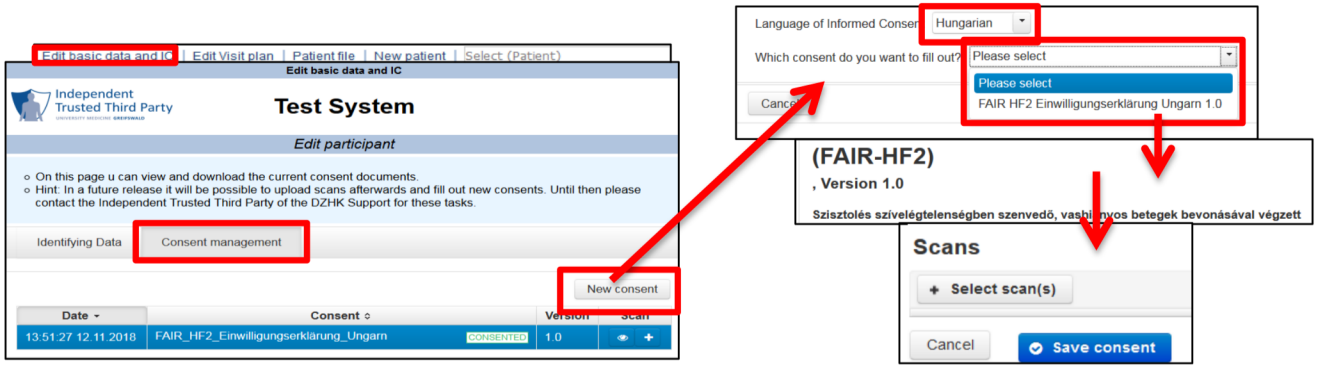


- Request an upload ticket via e-mail. Using this ticket, you can send the file note to informed consent to the TTP (see SOP "Requesting and submitting tickets").
- Redeem the upload ticket. Before completing the process, please verify that you've uploaded the correct files.

Case 4: Discrepancies between optional modules or date of signature of the IC-scan and the digital IC (filled in digitally):

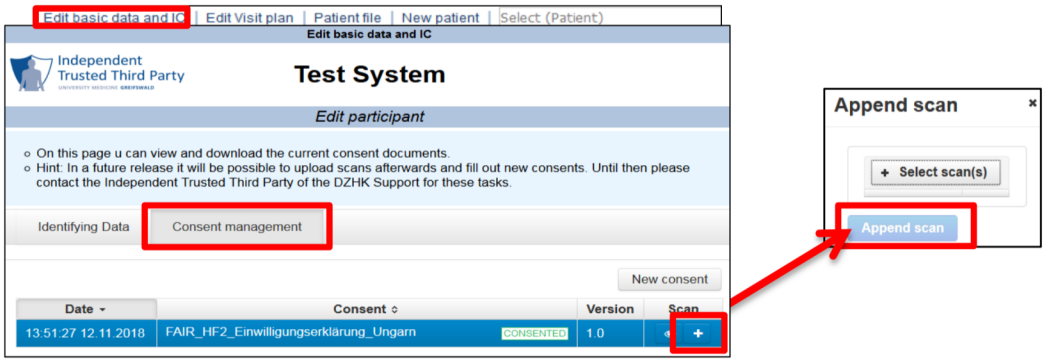
If the IC-scan is correct:

- Search for the corresponding pheno-pseudonym in secuTrial.
- Create and fill in a new digital IC based on the IC-scan using the secuTrial-tab "Edit basic data and IC " (see SOP "DZHK-SOP-TTP-01 Acquisition-IDAT-Informed Consent").Please also upload the respective IC-scan.



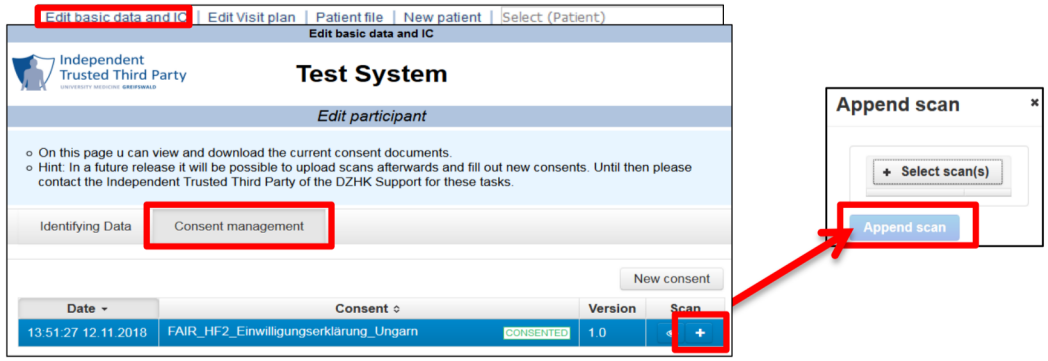
If the IC-scan is incorrect

- Contact the study participant and ask her/him to fill in a new consent form.
- Scan the new consent form.
- Search for the corresponding pheno-pseudonym in secuTrial.
- Upload the corrected IC-scan using the secuTrial-tab "Edit basic data and IC" (see SOP "DZHK-SOP-TTP-01 Acquisition-IDAT-Informed Consent").



Case 5: IC-scan is missing:

- Search for the corresponding pheno-pseudonym in secuTrial.
- Upload the IC-scan using the secuTrial-tab "Edit basic data and IC" (see SOP "DZHK-SOP-TTP-01 Acquisition-IDAT-Informed Consent")



If you have any questions, please feel free to contact us via telephone (+49 3834/86-7588) or e-mail.