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

DZHK-SOP-THS-02_DE

Recording Revocation and Study Exclusion

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Content

1 List of Abbreviations

Abbreviation	Meaning
DZHK	Deutsches Zentrum für Herz-Kreislauf-Forschung e. V. (German Centre for Cardiovascular Research)
SE	Study Exclusion
SEF	Study Exclusion Form
SOP	Standard Operating Procedure
SC	Study Centre
TTP	Independent Trusted Third Party of the Central Data Management of the DZHK
RF	Revocation Form
R	Revocation

2 Change to the previous version

In version 1.7

- the procedure for archiving a revocation is described more precisely (cutting the pseudonym from the informed consent form);
- the study exclusion form has been included in the SOP.

3 Introduction

The scientific infrastructure of the German Centre for Cardiovascular Research (DZHK) is widely established. The current phase is focused on creating all the tools necessary for enrolling study participants and on specifying procedures. Still, recording revocations and the associated processes (execution of revocations) must be supported from the beginning of the DZHK study. The Trusted Third Party of the Central Data Management of the DZHK (TTP) will thus use the procedure described below for processing incoming revocations.

This SOP is based on the data protection concept of the DZHK Central Data Management (version 1.2 dated 24/03/2014) and on the ethics concept of the Clinical Research Department of the German Centre for Cardiovascular Research (DZHK) (version 2.0 dated 01/02/2016, currently in revision), referred to from here on as DZHK Ethics Concept.

The TTP can equally process personally identifiable information of patients and healthy volunteers. To ensure uniformity in the spoken and written form, the term “study participant” will be used. The term applies to both genders equally.

As the TTP will process revocations and study exclusions almost equally, the term “revocation” will be used mostly synonymously for both processes from here on**. Separate processes for revocation and study exclusion will be described in detail in section 6.1.**

Objective

The objective of the SOP is to specify the operating procedure for recording a revocation or study exclusion as well as to provide study staff instructions on how to handle this and how to properly complete the revocation form or study exclusion form.

Target audience

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

Scope

The SOP is valid for all primarily or completely funded clinical research projects conducted in the DZHK. Partially funded projects may also use the scientific infrastructure of the DZHK.

4 Background

Processing personally identifiable information (e.g. name, address) is the responsibility of the TTP, which is located at the University Medicine Greifswald. Data processing is thus subject to the provisions of data protection laws in Mecklenburg-Western Pomerania and whole Germany.
The technical, personnel, spatial and organisational measures that are essential for ensuring the necessary framework conditions are implemented were defined in a data protection concept that was discussed with the Data Protection Commissioners of Mecklenburg- Western Pomerania and Lower Saxony and for which a positive vote was issued.
The possible revocation measures supported by the DZHK have been defined in the DZHK Ethics Concept. Study-specific regulations have been defined in the relevant patient information sheet and informed consent form. These have received a positive vote from the regional ethics committees.

5 Requirements / Conditions

- Clinical study: Clinical trial in accordance with the German Medicinal Products Act (AMG) or the German Medical Devices Act (MPG) as well as other studies in accordance with the professional code of conduct (also including registers independent of another study, such as TORCH-DZHK1)
- The revoking study participant or the study participant to be excluded is participating in a DZHK study and is already known to the TTP.
- Study participant revocation is available in a form that complies with the DZHK Ethics Concept.

6 Processes

The process illustrated below (Figure 1) describes the revocation procedure between the study centre (SC) and the TTP. A more detailed illustration is available in Appendix 1. If a study participant revokes her/his participation, the revocation form (RF) must be completed and sent to the TTP (see section 6.1.1). However, if the study participant no longer meets the inclusion criteria, please complete the study exclusion form (SEF) (see section 6.1.2). The TTP will review the content and confirm receipt to the SC. After successful processing of the revocation, the TTP will document the execution on the RF and send the form back to the SC. The SC will then notify the study participant about the completed execution.

Please note:
Section 6.4 does **not** apply to studies conducted in accordance with german AMG and MPG regulations.
At present, this regulation applies to the following studies: APPROACH-ACS-AF-DZHK7, SMART-MI-DZHK9, FAIR-HF2-DZHK5.

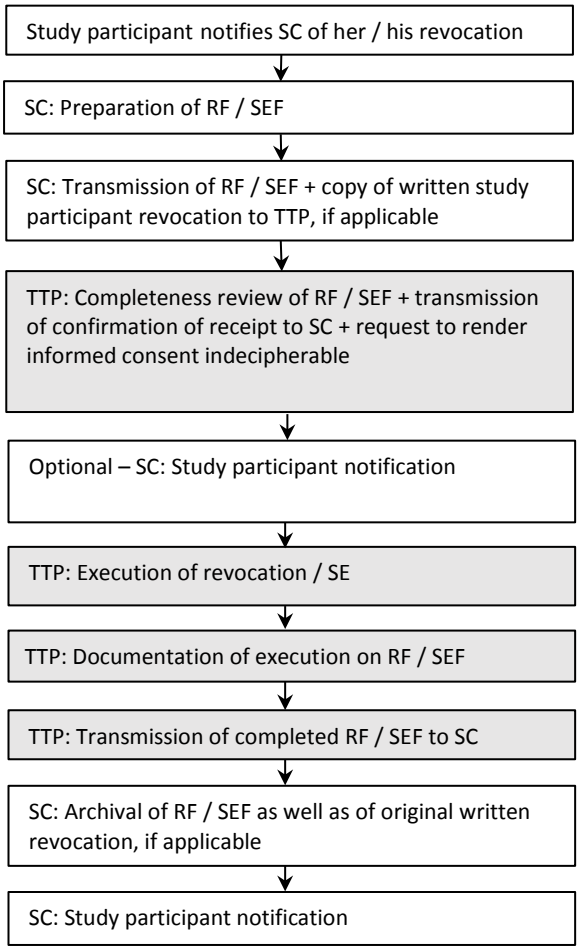

Figure 1: Revocation flowchart (short version)

6.1 Recording revocation and study exclusion at SC

6.1.1 Recording and transmission of revocation by SC

Only the SC may send revocations to the TTP in written form using the revocation form (RF).
In case of oral revocation by the study participant, the RF must be completed. If the study participant revokes by writing, a digital copy (scan) of the written revocation must be sent to the TTP in addition to the completed RF.

In the upper section of the form, enter the study and the study centre details, and the blocks "Revoking participant" and "Study centre member recording revocation" must be completed. Ensure that the participant information (surname, forename, date of birth as well as place of birth) is fully recorded, as only these information can ensure clear identification of the participant at the TTP. Missing information must be researched in secuTrial or in the paper version of the informed consent form.
If revocation is provided by an authorised representative of the participant, the name and address of that person are to be recorded, and a copy of the written power of attorney is to be enclosed, if applicable.
Blocks "Receipt at Trusted Third Party (TTP)," "Revocation has been executed" as well as the comment field in the lower section of the revocation form are reserved for entries made by the TTP.

For studies **TORCH-DZHK1, VAD-DZHK3, and TOMAHAWK-DZHK4**, the patient may have her/his personally identifiable information (IDAT) held at the TTP deleted. If the patient submits such a request, this must be recorded in the form's comment field.

Please thoroughly review the information provided on the RF and sign the form.

TTP must be notified of any revocation within not later than one working day. Forms that include participant information must **never** be sent by email! Scans of the RF and, if applicable, the copy of the written revocation of the study participant must be sent to the TTP via upload ticket. More detailed information on this is available in DZHK-SOP-TTP-11 Requesting and submitting tickets.

6.1.2 Recording and transmission of study exclusion by SC

Only the SC may send SEs to the TTP in written form using the study exclusion form (SEF).
In the upper section of the form, enter the study and the study centre details, and block "Participant to be excluded" must be completed. Ensure that the participant information (surname, forename, date of birth as well as place of birth) is fully recorded, as only this will ensure clear identification of the participant at the TTP. Missing information must be researched in secuTrial or in the paper version of the informed consent form.
Block "Reason for exclusion" should be completed in such a way that the Central Data Management is able to assign further processing:

1. Violation of the inclusion and exclusion criteria:
   AFTER the study participant has been created in secuTrial, it is determined that the inclusion criteria are not met or that exclusion criteria apply.

Once violation of the criteria has been determined, no further assessments can be captured in secuTrial.

2. Deviation from the informed consent process:
   Irregularities are determined during the informed consent process / in the informed consent documents that cannot be resolved / clarified right away.
3. Erroneous / missing source documents:
   The requirement of data collection traceability is not met – corresponding documents contain errors or are missing.
4. Other reasons for exclusion are to be explained in the comment field.

Furthermore, the details of the SC staff member recording the exclusion must be entered into block "Staff member recording study exclusion."
Blocks "Receipt at Trusted Third Party (TTP)," "Revocation has been executed" in the lower section of the SEF are reserved for processing by the TTP.
Please thoroughly review the information provided on the SEF and sign the form.
TTP must be notified of any SE within one working day at the latest. Forms that include participant information must **never** be sent by email! A scan of the SEF must be sent to the TTP via upload ticket. More detailed information on this is available in DZHK-SOP-THS-11_DE_Ticketsystem.

6.2 Transmission of confirmation of receipt from TTP to SC

Following receipt of the RF, the TTP will review the information provided on the form. If the information is complete and correct and the revoking study participant can be clearly identified, the TTP will provide the date of receipt on the RF and send a confirmation of receipt to the study centre by email within five working days.

6.2.1 Missing confirmation of receipt from TTP to SC

If the TTP does *not* confirm receipt of an RF within five working days as described in Chapter 6.2, information on the receipt of the RF concerned must be requested from the TTP by phone. If the TTP is not able to confirm receipt, the RF must be resent to the TTP.

6.2.2 Revocation correction procedure

During quality assurance following receipt of the RF, the TTP will review the information provided on the RF. If information is illegible, missing or not clearly assignable to a known study participant (e.g. strongly deviating information on surname, forename, date of birth, place of birth), the TTP will not be able to execute the revocation.
In such a case, the TTP will contact the relevant SC and request a correct RF.

After all irregularities have been resolved, the TTP will execute and confirm the revocation.

6.3 Notification of study participant by SC

After the TTP has confirmed receipt of the revocation, the SC may notify the revoking participant (in writing) that deletion / anonymisation of her/his information and destruction of her/his biological material has been arranged in accordance with the Ethics Concept.

6.4 Rendering the pseudonym indecipherable on the informed consent form at the SC

Please note:
This section does **not** apply to studies conducted in accordance with german AMG and MPG regulations. At present, this regulation applies to following studies: APPROACH-ACS-AF-DZHK7, SMART-MI-DZHK9, and FAIR-HF2-DZHK5.
Please continue to section6.5.

The SC will informed within two days of confirmation of receipt and will be requested to render all Pheno-PSNs indecipherable. Several informed consent forms may be affected in case of implicit revocations. This currently applies to following ICs:

VAD study (DZHK3)	Implicit	VAD biological material collection
VAD register (DZHK3)	Implicit	VAD register – Biological material collection
TOMAHAWK study for patient or representative (DZHK4)	Implicit	TOMAHAWK biological material collection for patient or representative

The TTP will inform the SC about which ICs to edit. Furthermore, the SC is obligated to render any pseudonyms from any further documents indecipherable that may contain IDAT as well as the corresponding pseudonyms (e.g. master data sheet).

6.5 Recording and executing revocations at the TTP

The TTP will record the revocation in their software modules and notify all downstream sites concerned (such as biobank, research database). After all downstream sites have confirmed deletion / anonymisation of information and destruction of biological materials of the revoking participant, and if all other TTP procedures have been completed, the TTP will document the execution of the revocation on the RF and send the form back to the SC via download ticket.

Please do not destroy any biological materials **unless** you received a separate request from Central Data Management, and **do not destroy any paper documents**!

6.6 Study participant notification

After the TTP has confirmed execution of the revocation, the SC must notify the revoking participant that the anonymisation of her/his medical data and the destruction of her/his biological material have been executed successfully in accordance with the Ethics Concept.

6.7 Archival of RF as well as of original written revocation, if applicable

The returned RF as well as the original written revocation, if applicable, must be archived together with the informed consent form (at a locked location). The note “Revoked” or “Study exclusion” must be added to the informed consent form enclosed with the patient’s medical record.

7 Responsibilities

Study Centre

The SC is responsible for obtaining and forwarding the revocation and for archiving the revocation process as well as the study participant’s written revocation, if applicable. The SC furthermore is obligated to render the pseudonym indecipherable on the informed consent form and to notify the TTP of this. The SC is also responsible for notifying the study participant of the execution of the revocation. Additionally, the SC is the direct contact for study participants regarding revocations.

Trusted Third Party

The TTP is responsible for the electronic processing of the revocation. It also initiates all subsequent processes (e.g. deletion / anonymisation of information, destruction of biological material) to be executed by sites concerned in the revocation, and it notifies the SC of RF receipt as well as of the completed execution of the revocation.

Contact details of the DZHK’s Independent Trusted Third Party
Unabhängige Treuhandstelle des DZHK
an der Universitätsmedizin Greifswald
Institut für Community Medicine, Abt. VC
Ellernholzstr. 1-2
D-17487 Greifswald

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Email: ths-dzhk-support@uni-greifswald.de

8 Literature and references

- Data protection concept of the DZHK's Central Data Management (version 1.1 of 27/08/2013)
- Data Protection Act for the German Federal State of Mecklenburg-Western PomeraniaR – DSG M-V (version of 28/03/2002)
  www.landesrecht-mv.de
- Ethics Concept of the Clinical Research Department of the German Centre for Cardiovascular Research (DZHK) (version 2.0 of 02/02/2016)

9 Persons involved in creating the SOP

Name	Role	Involvement
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Monika Kraus	Ethics Research Associate	Author and Reviewer
Thomas Bahls	Scientific Project Coordinator	Reviewer
Katrin Leyh	Medical documentalist	Author
Dana Stahl	IT Research Associate	Author and Reviewer

10 Applicable documents

- Revocation form in its most recent version
- Study exclusion form in its most recent version
- Data protection concept of the DZHK's Central Data Management (version 1.2 of 24/03/2014)
- Ethics Concept of the Clinical Research Department of the German Centre for Cardiovascular Research (DZHK) (version 2.0 of 01/02/2016)

Appendix 1

Process: revocation and study exclusion