Informing and consenting

Status	Genehmigt

Organisation	Departement Klinische Forschung
Kürzel	SOP EMINENT-ICH RCT 001

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Anmerkung

Das vorliegende Dokument ist eine Kopie aus der Applikation «Orca». Das Original, respektive die aktuell gültige Version ist unter orca.dkfbasel.ch verfügbar.

Inhaltsverzeichnis

1. Introduction

Informing patients and/or their relative or an independent physician is a major cornerstone of patient recruition.

Informing and consenting of the patients or their relatives usually occurs via a study team member. The study team member informs about the purpose, procedures, risks and benefits of the trial. After consenting and answering potential questions, the informed consent will be signed by both the consenting study team member and the patient.

Herein follows the instruction on how to inform and consent patients for the EMINENT-ICH trial, especially how the consent procedure in emergency situations has to be.

This process is complete when the informed consent was signed by both parties.

2. Scope

This SOP is valid for the EMINENT-ICH trial.

3. Terms and abbreviations

ICF: Informed consent form

ICH: intracerebral haemorrhage

CRF: Case report form

ISF: Investigator site file

4. Roles and Responsibilities

Sponsor

Trial oversight

Principal Investigator (incl. Local PI)

Oversight over study site and responsibility for correct informed consent procedure

Study personnel

Choosing correct ICF and consenting patient

5. Process

Patients get admitted to the emergency department of the respective site with suspected ICH. Study eligibility is confirmed by the study team on-site.

After eligibility is confirmed, one of two scenarios takes place:

1. The patient is able to consent by him/herself. This means that the patient is able to grasp the scope of the study and the risk and benefits it may entail.
2. The patient is **not** able to consent him/herself due to various reasons (i.e. decreased consciousness)

5.1. Scenario one - Patient is able to consent him/herself

In case of **scenario one**, the patient will receive the ICF for prospective patients (EMINENT_RCT_Patient_prosp_V1.1_250123.pdf[1]). He/she is informed about the purpose, procedures, risks and benefits of the trial by the investigator using the ICF.

The investigator will pay special attention to mention that this study is **randomised**, meaning patiens are assined randomly, that **both treatments are valid treatment options according to the current guidelines** and that the surgical treatment has been tested before.

The investigator answers questions brought forth by the patient. Additionally, the patient will be asked to complete the ICF for further use of his/her data, which is an extension of the ICF for this study.

If the patient is satisfied with the extend of explanation and consents for participating in the trial, both, the investigator and the patient, will sign the ICF for

1) the study participation and eventually also

2) for further use of data.

With that, the patient confirms his participation in the trial and agrees that his data might be used for further research. If requested, a copy of the ICF will be handed out to the patient.

The ICF will be filed in the study participants CRF folder and a remark in the respective patients electronic files about informed consent to participate will be made (i.e. “Patient XY has agreed to participate in the EMINENT-ICH trial”).

5.2. Scenario two - Patient is not able to consent him/herself

In case of **scenario two**, the investigator will make sure, that an participation in this trial is in the patients best interest (i.e. by consulting a do-not-resucitate order). He/she then consults an independent physician (i.e. a physician not delegated in the trial) to confirm that the patients interest are preserved (Indepent_physician_EMINENT_V1_251122.pdf[2]).

If the independent physician confirms that the interest of the patient are preserved, the patient is included in the trial and the confirmation will be filed in the participants CRF folder

and a remark will be made in the patients electronic file.

In case, that the patient will remain permanently impaired, his/her relatives or legal guardian will be retrospectively informed and consented about the study participation of the patient (EMINENT_RCT_Relatives_retro_V1.1_250123.pdf[1]). The relative is informed about the purpose, procedures, risks and benefits of the trial by the investigator using the ICF.

The investigator will pay special attention to mention that this study is **randomised**, meaning patiens are assined randomly, that **both treatments are valid treatment options according to the current guidelines** and that the surgical treatment has been tested before.

The retrospective ICF of the relative will be filed additonally to the confirmation of the independent physician in the study participants CRF folder and a remark in the patients electronic files about informed consent to participate will be made (i.e. “patient XYs relatives retrospectively consented to XYs participation in the study”).

If the patient, during the course of the study, should regain his ability to consent him/herself, the investigator will retrospectively consent the patient about his participation in the study (EMINENT_RCT_Patient_retro_V1.1_250123.pdf[2]).

The retrospective ICF will be filed additonally to the confirmation of the independent physician and the relatives in the study participants CRF folder and a remark in the patients electronic files about informed consent to participate will be made.

5.3. Pregnancy during the study

In case a patient gets pregnant during the study, she will have to consent to be followed troughout her pregnancy to confirm that the study treatment did not inflict harm on the patient or the baby. Patients receive an ICF for pregnancy (EMINENT-ICH_pregnant_V1.0_250123.pdf[3]). She is informed about the purpose, procedures, risks and benefits of the pregnancy follow-up by the investigator using the ICF.

1. https://orca.dkfbasel.ch/download/process/ae265e10-0c3c-11ee-9aee-0242ac120016
2. https://orca.dkfbasel.ch/download/process/02d8d9a3-0c3d-11ee-9aee-0242ac120016
1. https://orca.dkfbasel.ch/download/process/20aa3413-0c3d-11ee-9aee-0242ac120016
2. https://orca.dkfbasel.ch/download/process/43f524fb-0c3d-11ee-9aee-0242ac120016
3. https://orca.dkfbasel.ch/download/process/0fd017e7-0c3e-11ee-9aee-0242ac120016

6. Process diagram

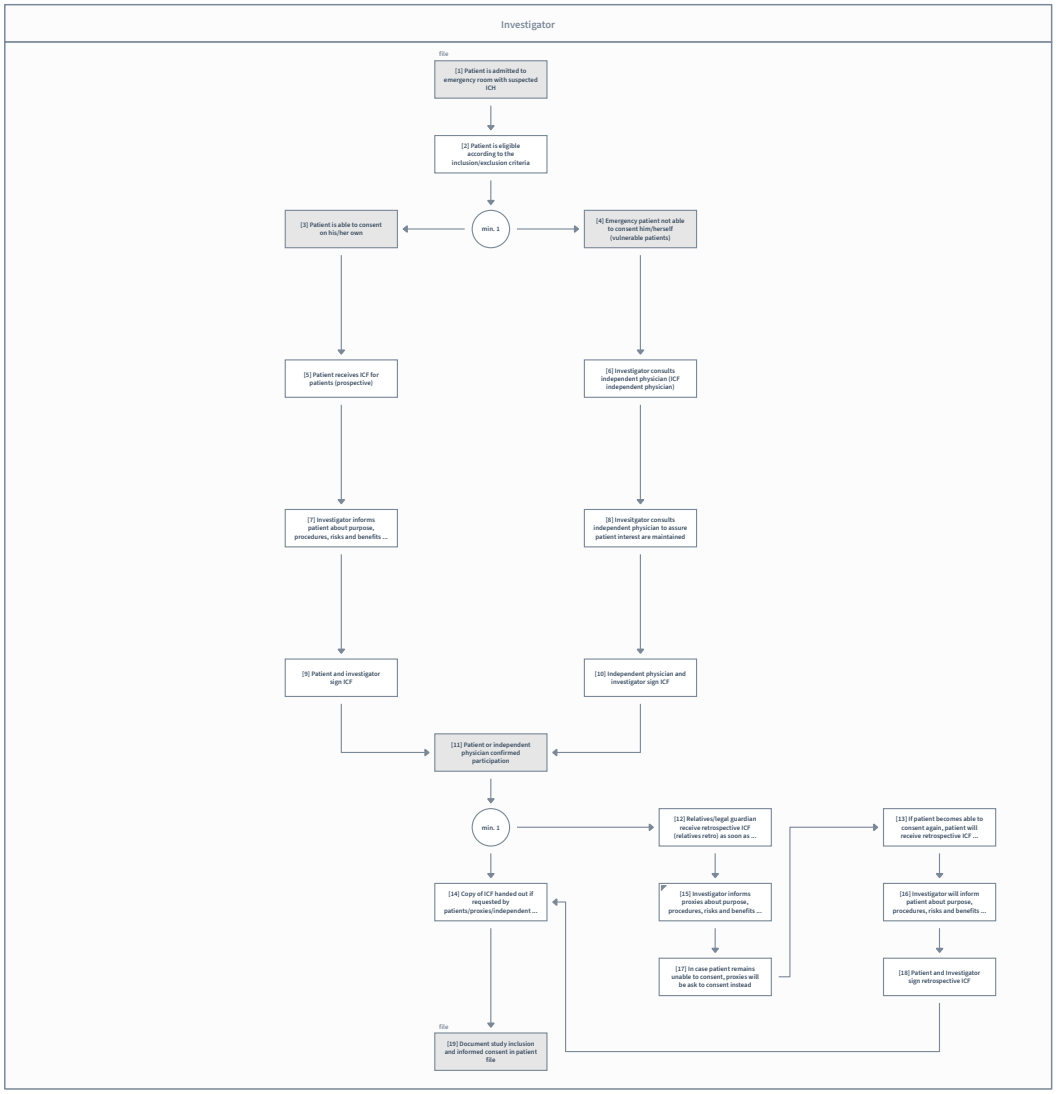

Diagramm 1

7. Metrics

ICF forms filed in the ISF per patient.

8. Document filing

The ICFs will be filed in the patients CRF folder and later 1) scanned and filed in the electronic study folder as backup and 2) the originals will be filed in the ISF of the respective site.

9. References (noch verlinken)

- EMINENT_RCT_Patient_prosp_V1.1_250123.pdf[1]
- Indepent_physician_EMINENT_V1_251122.pdf[2]
- EMINENT_RCT_Relatives_retro_V1.1_250123.pdf[3]
- EMINENT_RCT_Patient_retro_V1.1_250123.pdf[4]
- EMINENT-ICH_pregnant_V1.0_250123.pdf[5]
- https://swissethics.ch/assets/kinder_notfall/notfallsituationen_swissethics_d.pdf[6]
- https://swissethics.ch/assets/kinder_notfall/notfallsituationen_swissethics_f.pdf[7]
- https://swissethics.ch/assets/kinder_notfall/notfallsituationen_swissethics_i.pdf[8]

1. https://orca.dkfbasel.ch/download/process/a1f103e9-0c41-11ee-9aee-0242ac120016
2. https://orca.dkfbasel.ch/download/process/abe2ed4f-0c41-11ee-9aee-0242ac120016
3. https://orca.dkfbasel.ch/download/process/b64e6f94-0c41-11ee-9aee-0242ac120016
4. https://orca.dkfbasel.ch/download/process/c29584dc-0c41-11ee-9aee-0242ac120016
5. https://orca.dkfbasel.ch/download/process/cd1f4af0-0c41-11ee-9aee-0242ac120016
6. https://swissethics.ch/assets/kinder_notfall/notfallsituationen_swissethics_d.pdf
7. https://swissethics.ch/assets/kinder_notfall/notfallsituationen_swissethics_f.pdf
8. https://swissethics.ch/assets/kinder_notfall/notfallsituationen_swissethics_i.pdf

10. Details zu Diagramm 1

[1] Patient is admitted to emergency room with suspected ICH

[2] Patient is eligible according to the inclusion/exclusion criteria

[3] Patient is able to consent on his/her own

[4] Emergency patient not able to consent him/herself (vulnerable patients)

[5] Patient receives ICF for patients (prospective)

[6] Investigator consults independent physician (ICF independent physician)

[7] Investigator informs patient about purpose, procedures, risks and benefits of the study

[8] Invesitgator consults independent physician to assure patient interest are maintained

[9] Patient and investigator sign ICF

[10] Independent physician and investigator sign ICF

[11] Patient or independent physician confirmed participation

[12] Relatives/legal guardian receive retrospective ICF (relatives retro) as soon as possible

[13] If patient becomes able to consent again, patient will receive retrospective ICF (patients retro)

[14] Copy of ICF handed out if requested by patients/proxies/independent physician

[15] Investigator informs proxies about purpose, procedures, risks and benefits of the study

[16] Investigator will inform patient about purpose, procedures, risks and benefits of the study

[17] In case patient remains unable to consent, proxies will be ask to consent instead

[18] Patient and Investigator sign retrospective ICF

[19] Document study inclusion and informed consent in patient file

Änderungsverzeichnis

Version	Beschreibung
Version: 3.0.2 (aktuell)	03.03.2023: Initial version created of IC SOP according to template V 3.0.2 of the DKF