Standard Operating Procedure (SOP)

Informed Consents and Revocations

Educational Setting

Version 2.0

1. Aim

The aim of this SOP is to describe how to obtain consent and how to record and process a complete or partial withdrawal of consent. Processes for the deletion of personal data are also described.

2. Scope of the SOP

This SOP applies to the oral information provided to participants prior to signing the consent form for participation in the study and the consent form itself.

3. Abbreviations

gICS	Generic informed consent service
ID	Identification number
PDF	Portable Document Format
RM	Regional Management
SOP	Standard Operating Procedure
UMG	University Medicine Greifswald

4. Background

Before participating in the study, each potential participant/parent must be informed about the aim of the study, the voluntary nature of participation, study procedure, storage of data, renewed contact, data protection and revocation.

During the information meeting, the potential participant receives the participant information and the informed consent form. Each participant/parent must be given sufficient opportunity to ask questions in the classroom or individually and basic aspects of the consent form must be addressed. By agreeing to participate and by signing the consent form, the participant/parent gives their written consent and at the same time assures that they have understood everything and that there was an opportunity to ask questions, which can, however, also be done at any later stage.

During the consent process, a member of the Regional Management (RM) or a trained teacher goes through the sections of the consent form with the participant in group of other students and parents or individually if a student or parent prefers. If the parents or students would like more time to think about it, the consents can also be submitted later within 7 days.

If the parent does not attend the information meeting, the student will later provide the information material and consent form to the parent. In this case, the signed declaration of consent can be submitted to the school within 7 days.

In addition, educating the participant/parent requires an increased level of attention regarding data protection.

Each participant/parent is informed during the clarification and in the declaration of consent that they can declare their complete or partial revocation at any time to the RM responsible for them

without giving reasons. By revoking a consent, the participant/parent prohibits EUthyroid2 from carrying out a process that they had previously consented.

If a consent that allows data storage has been revoked, the affected data of the participant must be deleted.

5. Processes of obtaining consent

Personnel requirements

Only trained persons will be used for informing and obtaining consent from participants at the educational settings in the EUthyroid2 project. The training will be provided by the RM.

Equipment and materials required

- Study information
- Consent forms (paper-based)
- Contact information sheet (name, date of birth, address, Telephone number, e-mail)
- Paper-based informed consents: Computer in office of the participant management with access to gICS (Login: user name, study region, password, SSL clients certificate provided by UMG) or
- Digital informed consents using local system and subsequent transfer to gICS: Computer in office of the participant management with access to gICS (Login: user name, study region, password, SSL clients certificate provided by UMG)
- Consumables: Paper, Envelopes, IDs

Procedure of explaining the study to the participants

Firstly, the participant/parent should be welcomed and asked to participate in the EUthyroid2 study.

A member of the RM or the trained teacher will present the study and provide detailed information on the participant information. The following general conditions should be ensured:

- No interference from third parties (such as calls during the information meeting etc.)
- Sitting at a table (e.g. in a classroom)
- The participant/parent should be able to see the informed consent and the selection of consents on the monitor or on the paper
- Try to establish a facilitating interpersonal contact (e.g. eye contact, letting participants/parents finish speaking and listening attentively).
- Answer the participant's/parent’s questions and in detail and, if necessary, support them with examples
- Don't push the participant/parent to take part in the study, if they signal otherwise

In the event that the teacher collects the informed consent, only a paper-based consents can be used

A printed consent form and an envelope labelled PM2 should always be available, as the digital survey could also be disrupted by technical difficulties

During the information meeting, the staff of the RM or the trained teacher should give a brief summary of what the participant can expect during the intervention study.

- Organisational and timeframe:
    - Duration of the study
    - Ask if there are any questions on the course of the study
- Filling out the informed consent:

  a) Paper-based informed consents:
  1 exemplar of the signed paper-based consent gets the participant. The other exemplar will be placed in the A5 envelope labelled PM2 and sealed. This is collected by staff from the study regions. The participant management will then transfer the consents to the gICS.

  b) Digital informed consents:
  The participant should receive a copy of the signed informed consent. A copy of the signed informed consent should be printed in case of data loss unless your institution runs a full backup-and data archiving system.

Aspects after explaining the study information and consent forms

If the participant/parent expresses the wish to read through the informed consent or individual sections of it again in silence, this must be ensured, and any questions can then be clarified in a conversation.

Criticism and questions from the participants

The participant/parent must be informed that they can ask questions at any time, including by telephone after the study has started at the educational setting. If a question cannot be answered directly by a staff of the educational setting, for example, because it requires specific knowledge, this should be communicated openly and the question should be passed on to the RM so that they can contact an appropriate expert, if necessary. The participant/parent should be informed of this procedure and a prompt response should be ensured.

If the participant/parent does not want to participate in a specific part of the intervention during the course of the study, they can refuse to do so at any time, even if consent has previously been given in writing. In this case, the study should be explained in more detail in order to eliminate possible concerns.

6. Processes of revocation

The consent of a participant is the permission for EUthyroid2 to carry out further processes (e.g. data collection or to save or store data).

The revocation of the declaration of consent must generally be declared in writing or verbally. A participant's revocation of the declaration of consent can be revoked entirely or in part. In the event of a partial revocation, a participant/parent can individually revoke any consent that they have previously given and that is still valid. The revoked consents will be processed by the responsible RM. All changes to consent-relevant documents are recorded in the responsible RM.

Depending on which consent (questionnaire or interview) has been revoked, the consequence may be that a process may no longer be carried out, e.g. that – if data protection consent is revoked – data must be deleted or destroyed.

The deadlines for implementing revocations are 60 days beginning from the day the revocation is received by EUthyroid2. If a cancellation-related consultation with the participant/parent is necessary, the start of the deadlines is delayed by the time required to clarify the matter; however, it should take no longer than a maximum of 21 calendar days.
Within the responsible RM, the revoked consent should be processed immediately afterwards, but no later than after 5 working days.
The deletion of the survey and examination data should take place within 30 days.
At UMG, the deletion of pseudonyms or pseudonym assignments should take place immediately after the associated data has been deleted.

Brief overview of the revocation process

1. The participant/parent declares his/her revocation and sends this in writing to the Participant Management involved. Revocations by email or verbally are possible in cases to be determined by the Participant Management.
2. If the scope of the revocation is not clearly stated in the declaration or there are other ambiguities, the Participant Management will contact the participant/parent as soon as possible to answer any questions. The clarification of all open questions by the Participant Management may take a maximum of 21 calendar days.
3. No later than the 5th working day after the receipt of the declaration of revocation or after the facts have been clarified – if there are any open questions that need to be clarified with the participant/parent – the Participant Management involved will inform the UMG about the revocation.
4. UMG resets all revoked consents (from “Yes” to “No”) in gICS.
5. UMG informs the Participant Management
   <u>If no data deletion is necessary:</u>

6a) UMG informs the Participant Management who will send the participant a letter confirming the implementation of the revocation. [The process ends here.]

<u>If data protection consent has been revoked and the corresponding data has been saved or stored:</u>

6b) The Participant Management sends the participant/parent a letter confirming the receipt of the revocation.

7. UMG informs the Participant Management who arranges the data deletion at all affected EUthyroid2 data processing facilities that store survey and examination data of the participant.
8. The data processing facilities delete this data and send a data deletion destruction confirmation to the Participant Management.
9. Once all confirmations have been received by the Participant Management involved, the revocation has been implemented.
10. Then, the Participant Management sends the participant/parent a letter confirming the implementation of the revocation.
    [The process ends here.]