# Standard Operating Procedure (SOP)

## Informed Consents and Revocations

## Ambulatory Care 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 or destruction of urine samples of a study participant 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 intervention study and the consent form itself.

## 3. Abbreviations

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

## 4. Background

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

During the information session, the potential participant receives the participant information and the informed consent form. Each participant must be given sufficient opportunity to ask questions and basic aspects of the consent form must be addressed. By agreeing to participate and by signing the consent form, the participant 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, the healthcare professional goes through the sections of the consent form with the participant. In addition, educating the participant requires an increased level of attention regarding data protection.

Each participant 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 regional management responsible for them without giving reasons. By revoking a consent, the participant 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If a consent that allows data storage has been revoked, the affected data of the participant must be deleted. If a consent that affects the storage of urine samples has been revoked, the participant's urine samples must be destroyed.

# 5. Processes of obtaining consent

## Personnel requirements

Only trained healthcare professionals will be used for informing and obtaining consent from participants in the EUthyroid2 project. The training will be provided by the regional management.

## 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 should be welcomed and asked to participate in the EUthyroid2 study.

A healthcare professional 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 conversation, call waiting, etc.)
- Sitting at a table
- The participant 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 finish speaking and listening attentively).
- Answer the participant's questions and in detail and, if necessary, support them with examples
- Don't push the participant to take part in the study, if they signal otherwise

Login to gICS or have the printed consent forms (A4 Envelope labelled PM1) available in advance.

While the study information is explained, the healthcare professional should give a brief summary of what the participant can expect during the conversation and in the study.

- Organisational and timeframe:
    - Duration of stay: baseline: 1st follow up; 2nd follow up:
    - Data and urine sample collection
    - For the intervention group: short explanation on the intervention, but not too detailed to not influence first measurement (information material in different forms about health and nutrition, especially with focus on iodine).
    - Ask if there are any questions on the course of the intervention 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 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 must be informed that they can ask questions at any time, including by telephone after visiting the ambulatory care setting. If a question cannot be answered directly by an employee on site, for example, because it requires specific knowledge, this should be communicated openly and the question should be passed on to the regional management so that they can contact an appropriate expert, if necessary. The participant should be informed of this procedure and a prompt response should be ensured.

If the participant 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 and urine samples).

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 (e.g the collection of urine sample will be revoked but not the questionnaire survey). In the event of a partial revocation, a participant can individually revoke any consent that they have previously given and that is still valid. The storage and use of urine samples can only be revoked entirely. The revoked consents will be processed by the responsible regional management. All changes to consent-relevant documents are recorded in the responsible regional management.

Depending on which consent 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 and urine samples must be deleted or destroyed.

Participants who withdraw their consent to the processing and storage of urine samples will be asked whether they agree to the deletion of the linkage of their person. In this case the urine samples will

be processed in anonymised form. If the participant does not agree, the samples will be destroyed as described below and the corresponding data deleted.

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 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 regional management, 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 IMR, the destruction of the urine samples and the associated information in the laboratory management software 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 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 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 – the participant management involved will inform the UMG and IMR about the revocation.
4. UMG resets all revoked consents (from “Yes” to “No”) in gICS.
5. UMG informs the participant management and IMR about the reset of the consents (and thus the blocking of data and urine samples).

<u>If no data deletion, urine sample destruction or contact data deletion in the laboratory management software 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 or urine samples have already been saved or stored:</u>

6b) The participant management sends the participant a letter confirming the receipt of the revocation.

7. UMG informs the participant management and IMR who arranges the data deletion and the destruction of urine samples at all affected EUthyroid2 data processing facilities that store survey and examination data or urine samples of the participant.
8. The data processing facilities delete this data or destroy the urine samples and send a data deletion or urine sample 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 a letter confirming the implementation of the revocation.
    [The process ends here.]