

Standard Operating Procedure (SOP)

Participant Management/Data management

Ambulatory Care Setting

Digital data collection

Version 2.0

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1. Aim

The aim of this SOP is to describe the participant management tasks and data management tasks of each study region that has opted for paper-based data collection

2. Scope of the SOP

The SOP applies to all participant management processes. The personally identifiable data must be processed with particular care and in accordance with the applicable General Data Protection Regulation.

3. Abbreviations

DM	Data Management
gICS	Generic Informed Consent Management System
gPAS	Generic Pseudonym Management System
ID	Identification number
IMR	Institute of Marine Research, Norway
PM	Participant Management
Pseudo-ID	Pseudonym Identification number
QR-Code	Quick Response Code
SOP	Standard Operating Procedure
UMG	University Medicine Greifswald

4. Background

In Euthyroid2, health data from voluntary study participants is collected pseudonymised. To ensure pseudonymisation, all personally identifiable data will be processed separately from the collected study data. Similarly, employees who have access to the personally identifiable data will not have access to the collected study data.

The participant management is responsible for managing the contact details of study participants and participating ambulatory care facilities, preparing all study documents and materials, assigning the corresponding identification numbers, managing consent forms and revocations. In addition, it will be responsible for confirming appointments and, if necessary, implementing response-enhancing measures such as appointment reminders for follow-up surveys. The participant Management is the central communication point for study participants and healthcare professionals from the participating ambulatory care facilities.

5. Processes of the participant management

Personnel requirements

The employees who process the personally identifiable data must be familiar with the most important rules of data protection and be confident in handling health data. A signed confidentiality agreement should also be in place. If this has not already been done when the employment contract is concluded, it should be obtained before starting work in participant management for EUthyroid2

Equipment and materials required

- Computer with Internet connection to get access to Pseudonym Management System (gPAS) and Informed Consent Management System (gICS) (Access: user name, study region, password, SSL clients certificate provided by UMG)
- Telephone station
- QR-Code/Barcode-Scanner
- Interview recording hardware and if necessary interview recording software
- Telephone number and email-address for participants and ambulatory care facilities
- Study information
- Consent forms (as view copy)
- Sticker sheet with Pseudonym (Pseudo-ID)
- Awareness questionnaire (as view copy)
- Evaluation questionnaire (as view copy)
- Iodine Feedback Tool (as view copy)
- Labelled material for urine sample processing
- Contact information sheet (name, date of birth, address, Telephone number, e-mail, appointments)
- Appointment card (at least 3 appointment fields: Baseline, 1st Follow-up, 2nd Follow-up, contact information of participant management)
- Consumables: Paper, Envelopes

Access to Pseudonym Management System (gPAS) and to Informed Consent Management System (gICS)

Firstly, UMG must be informed of the full name and work e-mail address of the respective employee by e-mail.

UMG will then create a personal certificate for each employee and send it to the service e-mail address provided. Instructions for importing the certificate into the web browser are also provided.

UMG communicates the password for the certificate via video conference and, if necessary, provides support for importing the certificate into the web browser.

5.1. T0-1: Before Training (only intervention group)

5.1.1. Preparation of study documents for healthcare professionals at T0-1

- Provide all required documents
 - Digital informed consent for the respective ambulatory care facility with Pseudo-ID
 - Sticker sheet with same pseudonym (Pseudo-ID) as on the informed consent
 - Contact information sheet
 - QR-Code/Barcode for **Awareness Questionnaire ACS T0-1** in LimeSurvey

Register the pseudonyms for T0-1 in gPAS

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Ambulatory Care" or "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Healthcare Professionals" as group
- Click "ok"
- Place the cursor in the field "Pseudonym"
- Use a QR/barcode scanner to scan the barcode of the informed consent in the selected field (alternatively, the pseudo ID can also be typed in)
- Place the cursor in the respective fields of Questionnaires for T0-1 and scan the barcode or type in the ID below the barcode
- Scroll down and click submit
- Check for correctness and click "submit pseudonyms"

Prepare the participant management envelopes for T0-1

- Label an A4 envelope with **HP-PM 1** and stick the pseudo ID on the envelope
- Stick the pseudo- ID on the contact information sheet
- Label an A5 return envelope with **HP-PM 2**
- **Place in the envelope HP-PM 1 the following:**
 - **Contact information sheet**
 - A5 return envelope labelled "**HP-PM 2**"
 - Paper containing the QR-Code/Barcode for **Awareness Questionnaire ACS T0-1** in LimeSurvey
- Seal the envelope

Prepare the data management envelopes for T0-1

Not applicable

Store envelope until the recruiter or data collector picks them up

5.2. T0-2: After Training (only intervention group)

5.2.1. Preparation of study documents for healthcare professionals at T0-2

- Provide all required documents
 - Same sticker sheet with pseudonym (Pseudo-ID) used for informed consent and for T0-1
 - Paper containing the QR-Code/Barcode for **Awareness Questionnaire ACS T0-2** in LimeSurvey

Register the pseudonyms for T0-2 in gPAS

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Ambulatory Care" or "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Healthcare Professionals" as group
- Click "ok"
- Place the cursor in the field "Pseudonym"
- Use a QR/barcode scanner to scan the barcode of the pseudonym and store it in the input field "pseudonym" in gPAS (alternatively, the pseudo ID can also be typed in)
- Place the cursor in the respective fields of Questionnaires for T0-2 and scan the barcode or type in the ID below the barcode
- Scroll down and click submit
- Check for correctness and click "submit pseudonyms"

Prepare participant management documents T0-2

Not applicable

Prepare the data management documents T0-2

- Label an A4 envelope with **HP-DM3** and stick the pseudo ID on the envelope
- **Place in the envelope HP-DM3 the following:**
 - Paper containing the QR-Code/Barcode for **Awareness Questionnaire ACS T0-2** in LimeSurvey
- Seal the envelope

5.3. T1: Baseline survey (intervention group and control group)

5.3.1. Preparation of study documents for participants at T1

- Provide all required documents
 - Digital informed consents with pseudo-ID
 - **Please note whether you prepare a participant from the intervention or the control group. There are separate lists with pseudo-IDs for informed consents for both groups.**
 - Sticker sheet with same pseudonym (Pseudo-ID) as on the informed consent
 - Study information (Flyer)
 - Contact information sheet
 - Appointment card
 - Paper containing the QR-Code/Barcode for **Awareness Questionnaire ACS T1** in LimeSurvey
 - **Please note whether you are preparing the documents for the intervention group or the control group. There are separate lists with access codes for both groups**
 - Factsheet (**only intervention group**)
 - Paper containing the QR-Code/Barcode for Iodine Feedback Tool (**only intervention group**)
- Unpack the urine sample material for **T1** so that it is ready for scanning the IDs
- Label the urine collector with the same pseudonym sticker
- Label the box/package with the remaining materials for urine collection (this will help you to proceed later)

Register the pseudonyms for T-1 in gPAS

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Ambulatory Care" or "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Participants" as group
- Select "Intervention group" or "control group" depending on the participant you prepare
- Click "ok"
- Place the cursor in the field "Pseudonym"
- Use a QR/barcode scanner to scan the barcode of the informed consent in the selected field (alternatively, the pseudo ID can also be typed in)
- Place the cursor in the respective fields of Questionnaires for T-1 and scan the barcode or type in the ID below the barcode
- Place the cursor in the respective fields of urine sample for T-1 and scan or type in the ID from the urine collector
- **Only for intervention group:** Place the cursor in the respective fields of iodine feedback tool for T-1 and scan the barcode or type in the ID below the barcode
- Scroll down and click submit
- Check for correctness and click "submit pseudonyms"

Prepare the participant management envelopes for T1

- Label an A4 envelope with **P-PM 1** and stick the pseudo ID on the envelope
- Stick the pseudo- ID on the contact information sheet
- Label an A5 return envelope with **P-PM 2**
- **Place in the envelope P-PM 1 the following:**
 - Contact information sheet
 - Appointment Card
 - Study information (Flyer)
 - A5 return envelope labelled **P-PM 2**
 - Paper containing the QR-Code/Barcode for T1 (**Awareness Questionnaire ACS T1**)
 - Paper containing the QR-Code/Barcode for Iodine Feedback Tool (**only intervention group**)
 - Fact sheet (**only intervention group**)
 - ID-containing Urine collector with yellow lid (label “pre”)
- Seal the envelope

Prepare the data management envelopes for T1

Not applicable

Store envelope until the recruiter or data collector picks them up

5.4. T0-3: 50% of baseline survey achieved (only intervention group)

5.4.1. Preparation of study documents for healthcare professionals at T0-3

- Provide all required documents
 - Same sticker sheet with pseudonym (Pseudo-ID) used for informed consent and for T0-1 and T0-2
 - Paper containing the QR-Code/Barcode for **Questionnaire Process Evaluation T0-3** for healthcare professionals

Register the pseudonyms for T0-3 in gPAS

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Ambulatory Care" or "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Healthcare Professionals" as group
- Click "ok"
- Place the cursor in the field "Pseudonym" and use a QR/barcode scanner to scan the Pseudo-ID (alternatively, the pseudo ID can also be typed in)
- Place the cursor in the respective fields of the Questionnaire for T0-3 and scan or type in the ID below the barcode
- Scroll down and click submit
- Check for correctness and click "submit pseudonyms"

Prepare the participant management envelopes for T0-3

Not applicable

Prepare data management envelopes for T0-3

- Label an A4 envelope with **HP-DM5** and stick the pseudo ID on the envelope
- **Place in the envelope HP-DM5 the following:**
 - Questionnaire for T0-3 (**Questionnaire Process Evaluation T0-3**) for healthcare professionals

5.5. T0-4: Process evaluation interview (only intervention group)

5.5.1. Preparation of study documents for healthcare professionals at T0-4

Regional management will interview **two healthcare professionals** who delivered the intervention per region and will receive all necessary information by the project partners

- Provide all required documents
 - Same sticker sheet with pseudonym (Pseudo-ID) used for informed consent and for T0-1, T0-2 and T0-3
 - Guidelines for Interviews
 - ID for interview file
- Audio recording device

Register the pseudonym for T0-4 in gPAS

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Ambulatory Care" or "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Healthcare Professionals" as group
- Place the cursor in the field "Pseudonym" and use a QR/barcode scanner to scan the Pseudo-ID
- Place the cursor in the respective fields of the Interview for T0-4 and scan the ID
- Scroll down and click submit
- Check for correctness and click "submit pseudonyms"

Prepare participant management envelopes for T0-4

Not applicable

Prepare data management envelopes for T0-4

- Label an A4 envelope with **HP-DM7** and stick the pseudo ID on the envelope
- Label an A4 return envelope with **HP-DM8**
- **Place in the envelope HP-DM7 the following:**
 - Guidelines for Interviews
 - ID for interview file
 - Audio recording device
 - A4 return envelope labelled **HP-DM8**

5.6. T2: Follow-Up (intervention group and control group)

5.6.1. Preparation of study documents for participants at T2 (2-4 weeks after intervention/baseline)

Appointment management T2

The agreed appointments should be checked regularly in the Access database or in the participant's own system.

If no follow-up appointment has yet been made, the participant management team will contact the outpatient care facility and the participant at least 2 weeks before the end of the 6-week period to arrange an appointment.

The study documents for the Follow-ups can either be brought to the ambulatory care facility or sent home to the participant. For the latter, a corresponding cover letter should be prepared and sent along.

5.6.2. Preparation of study documents at T2

- Provide all required documents
 - Paper containing the QR-Code/Barcode for **Awareness Questionnaire ACS T2**
 - **Please note whether you are preparing the documents for the intervention group or the control group.**
 - Same sticker sheet with pseudonym (Pseudo-ID) used for informed consent and for T-1
 - 2 Appointment Cards for T3 (1 for participant, 1 for participant management)
- Unpack the urine sample material for **T2 (check if it is labelled with the right pseudo-ID)** so that it is ready for scanning the IDs
- Label the urine collector with the same pseudonym sticker

Register pseudonyms for T2 in gPAS

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Ambulatory Care" or "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Participants" as group
- Select "Intervention group" or "control group" depending on the participant you prepare
- Click "ok"
- Place the cursor in the field "Pseudonym" and scan or type in the Pseudo-ID
- Place the cursor in the respective fields of the Questionnaire for T2 and scan or type in the ID below the barcode
- Place the cursor in the respective fields of the urine samples T2 and scan or type in the ID from the urine collector
- Scroll down and click submit
- Check for correctness and click "submit pseudonyms"

Prepare participant management envelopes for T2 (only if there is no appointment for T3 yet)

- Label an C3 envelope with **P-PM 3** and stick the pseudo ID on the envelope
- Stick pseudo-ID on 1 appointment card (for participant management)
- Label an C3 return envelope with **P-PM 4** and fold it
- **Place in the envelope P-PM 3 the following:**
 - 2 Appointment Cards (1 for participant, 1 for participant management with pseudonym)
 - Folded C1 return envelope labelled **P-PM 4**
- Seal the envelope

Prepare data management envelopes for T2

- Label an A4 envelope with **P-DM 3**
- Stick pseudo ID on envelope
- **Place in the envelope P-DM 3 the following:**
 - Paper containing the QR-Code/Barcode for **Awareness Questionnaire ACS T2**)
 - ID-containing Urine collector for T3
- Seal the envelope

Store both A4 envelopes together until the recruiter or data collector picks them up

5.7. T3: Follow-Up (intervention group and control group)

5.7.1. Preparation of study documents for participants at T3 (6-8 months after intervention/baseline)

- Provide all required documents
 - Paper containing the QR-Code/Barcode for **Awareness Questionnaire ACS T3**
 - Same sticker sheet with pseudonym (Pseudo-ID) used for informed consent and for T-1 and T-2
- Unpack the urine sample material for **T3 (check if it is labelled with the right pseudo-ID)** so that it is ready for scanning the IDs
- Label the urine collector with the same pseudonym sticker

Register pseudonyms for T3 in gPAS

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Ambulatory Care" or "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Participants" as group
- Select "Intervention group" or "control group" depending on the participant you prepare
- Click "ok"
- Place the cursor in the field "Pseudonym" and scan or type in the Pseudo-ID
- Place the cursor in the respective fields of the Awareness questionnaire for T3 and scan or type in the ID from the questionnaire
- Place the cursor in the respective fields of the urine samples for T3 and scan the ID from the urine collector
- Scroll down and click submit
- Check for correctness and click "submit pseudonyms"

Prepare participant management envelopes for T3

Not applicable

Prepare data management envelopes for T3

- Label an A4 envelope with **P-DM 5**
- Stick pseudo ID on envelope
- **Place in the envelope P-DM 5 the following:**
 - Paper containing the QR-Code/Barcode for **Awareness Questionnaire ACS T3**
 - ID-containing Urine collector for T3
- Seal the envelope

Store the envelope until the recruiter or data collector picks them up

5.8. T4: Interview with participants

5.8.1. Preparation of study documents T4

Four participants per region will be interviewed for process evaluation

- provide all required documents
 - Same sticker sheet with pseudonym (Pseudo-ID) used for informed consent and for T1, T2 and T3
 - ID for interview file
 - Guidelines for Interviews
- audio-recording device

Pseudonym management T4 (only if participant was chosen for interview)

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Ambulatory Care" or "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Participants"
- Select "Intervention group" or "control group" depending on the participant you prepare
- Click "ok"
- Place the cursor in the field "Pseudonym" and scan or type in the Pseudo-ID
- Place the cursor in the respective fields of the interview file for T4 and scan or type in the ID

Prepare participant management envelopes for T4

Not applicable

Data management documents T4 (only if participant was chosen for interview)

- Prepare an A4 envelope labelled **P-DM 7**
 - Stick pseudo ID on envelope
- **Place in the envelope P-DM7 the following:**
 - ID for interview file
 - Guidelines for Interviews
 - Audio-recording device and ID for interview file
 - A5 return envelope labelled **P-DM8**

6. Handling at the ambulatory care facility

6.1.1. T0-1: Informed Consents from Healthcare Professionals

- A member of the regional management will collect the informed consent as described in the SOP “Informed Consents and Revocations”. The healthcare professional will receive a copy (digital or printed).

6.1.2. T0-1: Questionnaire from Healthcare Professionals before training Only intervention group

- After the consent was conducted the member of the regional management hands over the paper with the QR-Code/Link for the Questionnaire T0-1 (Awareness & Process Evaluation) in LimeSurvey
- The healthcare professional will scan the QR-Code or type the link in the web browser leading to LimeSurvey
- The health care professional fills the questionnaire online in LimeSurvey

6.1.3. T0-2: Questionnaire from Healthcare Professionals after training Only intervention group

- A member of the regional management hands over the A4 envelope labelled **HP-DM3** containing the paper with the QR-Code/link for the Questionnaire T0-2 (Awareness & Process Evaluation) in LimeSurvey
- The healthcare professional will scan the QR-Code or type the link in the web browser leading to LimeSurvey
- The health care professional will fill both questionnaires.

6.1.4. T1: Informed Consents from Participants and appointment management

- The health care professional of the ambulatory care facility will open the A4 envelope labelled **P-PM1**.
- The informed consent will be collected as described in the SOP “Informed Consents and Revocations”. The participant will receive a copy (digital or printed).
- The participant is then asked to enter their contact details on the contact information sheet.
- The health care professional of the ambulatory care facility will arrange an appointment for the 1st follow-up after 2-4 weeks and, if the participant agrees, the 2nd appointment after 6-8 months after intervention/baseline. Dates are entered on the contact information sheet and on the appointment card.
- The appointment card will be given to the participant.
- If it is not possible to make an appointment, this can also be made by telephone at a later date. In this case, the participant calls the ambulatory care facility and arranges the appointments. The ambulatory care facility then forwards the appointments to the participant management.
- The completed contact information sheet is then placed in the A5 envelope labelled **P-PM2** together with the second signed copy of the consent form and sealed.

6.1.5. T1: Questionnaire from participants

- The healthcare professional will open the A4 envelope labelled P-DM1 and hand over the paper with the QR-Code/link for the Questionnaire for T1 in LimeSurvey and the Urine collector with yellow lid.
- The participant will scan the QR-Code or type the link in the web browser leading to LimeSurvey
- The Questionnaire for T1 is filled in LimeSurvey
- **Only Intervention group:** after the Awareness questionnaire was filled the intervention is carried out as described in the SOP "Intervention components".
- During the intervention the access codes to the iodine feedback tool is handed over by the healthcare professionals
- The iodine feedback tool will be filled by the participants.
- At the end an automatic feedback pops up

6.1.6. T0-3: Process Evaluation Questionnaires for healthcare professionals Only intervention group

- A member of the regional management will open the A4 envelope labelled HP-DM5 and hand over the paper with the QR-Code/link for the Questionnaire for T0-3 (Process Evaluation) in LimeSurvey
- The healthcare professional will scan the QR-Code or type the link in the web browser leading to LimeSurvey
- The health care professional will fill the Process Evaluation Questionnaire.

6.1.7. T0-4: Process evaluation interview for healthcare professionals Only intervention group

- Regional management will interview two healthcare professionals who delivered the intervention per region and will receive all necessary information by the project partners
- The interview will be audiotaped
- The audio file will be labelled/named with the interview ID.
- The audio file of the interview is then placed in the A5 envelope labelled **HP-DM8** and sealed.
- The staff of the regional management will collect the envelopes **HP-DM8**.

6.1.8. T2: Appointment management

- The health care professional of the ambulatory care facility will arrange an appointment for the 2nd Follow-up (6 months after intervention/baseline)
- If an appointment was already arranged before, the health care professional reminds the participant.
- Dates are entered on the appointment card.
- 1 appointment card will be given to the participant.
- The second appointment card is then placed in the C1 envelope labelled **P-PM4** sealed.
- If it is not possible to make an appointment, this can also be made by telephone at a later date. In this case, the participant calls the ambulatory care facility and arranges the

appointments. The ambulatory care facility then forwards the appointments to the participant management.

6.1.9. T2: Questionnaire for participants

- The healthcare professional will open the A4 envelope labelled **P-DM3** and hand over the paper with the QR-Code/link for the Questionnaire for T2 and the urine collector with yellow lid.
- The participant will scan the QR-Code or type the link in the web browser leading to LimeSurvey
- The staff of the study regions will collect the urine samples obtained and the envelope **P-DM4** at least once a week.

6.1.10. T3: Questionnaire for participants

- The healthcare professional will open the A4 envelope labelled **P-DM5** and hand over the paper with the QR-Code/link for the Questionnaire for T3 and the urine collector with yellow lid.
- The participant will scan the QR-Code or type the link in the web browser leading to LimeSurvey
- The participant fills Questionnaire for T3
- The staff of the study regions will collect the urine samples obtained and the envelope **P-DM6** at least once a week.

6.1.11. T4: Interview for participants

- Four participants per region will be contacted by the regional management and interviewed for process evaluation.
- **The interviews are conducted by a designated staff member from the regional management and not by the healthcare professional who delivered the intervention to them.**
- The interviews should be conducted after the respective participants filled-out their last questionnaires (T3) to avoid influencing their answering behaviour.
- The interviews will be audiotaped.
- The audio file will be labelled/named with the interview ID.
- The audio file of the interview is then placed in the A5 envelope labelled **P-DM8** and sealed.
- The staff of the regional management will collect the envelopes **P-DM8**

7. Handling at the regional management

7.1. Data for participant management

- The **HP-PM 1, P- PM2, P- PM4** envelopes are handed over to the participant management staff and are **only** opened by them.
- The participant management staff will enter the contact information of the participant and the date of data collection into the “contact database” into the Access database provided by the UMG. Alternatively, each region can also use its own system.
- The given consents will be transferred from the paper-based version to gICS **by the participant management staff** within 3 working days upon receipt
- The paper copy is then kept tightly sealed in a fireproof cabinet with restricted access. If it is not possible to store the documents in a fireproof filing cabinet, two backups can be created instead of one, provided they can be stored in different locations.

7.2. Urine samples

Urine samples will be processed immediately and stored upon receipt as described in the SOP “Urine sampling”

7.3. Data for data management

Professional Transcription of Interviews

- The **HP-DM8** and **P-DM8** envelopes are handed over to the **data management staff** and **are only opened by them.**
- The regional management will receive a link to upload the audio files in FILECLOUD – a cloud that abides European data protection laws.