

Standard Operating Procedure (SOP)

Participant Management/Data management

Educational Setting

Paper-based consents and digital data collection

Version 2.0

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1. Aim

The aim of this SOP is to describe the Participant Management (PM) tasks and Data Management (DM) tasks of each study region that has opted for digital data collection.

2. Scope of the SOP

The SOP applies to all PM and DM 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
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 PM is responsible for managing the contact details of study participants and participating schools, 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 schools.

5. Processes of the Participant Management (PM)

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 PM 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
- Devices with electronic signature function and internet access via web browser, e.g Tablet with Adobe Reader
- QR-Code/Barcode-Scanner
- Interview recording hardware and if necessary interview recording software
- Contact information sheet for teachers (name, school, telephone number, e-mail, appointments)
- Study information
- Sticker sheet with Pseudonym (Pseudo-ID)
- Consent forms containing pseudonym
- Awareness Questionnaire (as view copy)
- Process Evaluation Questionnaires (as view copy)
- Iodine Feedback Tool (as view copy)
- Identification numbers and access codes
- Contact information sheet teacher (name, school, telephone number, e-mail, appointments)
- Contact information sheet for students (name, date of birth, home address, school and class)
- 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

5.1.1. Preparation of study documents for teachers at T0-1

- Provide all required documents
 - Contact information sheet for teachers (name, school, telephone number, e-mail, appointments)
 - Two exemplars of the informed consents
 - Sticker sheet with pseudonym (Pseudo-ID)

Participant Management documents T0-1

- prepare A4 envelope labelled **T-PM 1**:
 - Stick the Pseudo-ID on the envelope
- **Place in the envelope T-PM 1 the following:**
 - Consent form **after recorded in gPAS**
 - Contact information sheet for teachers
 - A5 return envelope labelled "**T-PM 2**"

Data Management documents T0-1

Not applicable

5.2. T0-2: Informing the students and parents

5.2.1. Preparation of study documents for students and parents

- Provide all required documents
 - Contact information sheet for students (name, date of birth, home address, school and class)
 - Two exemplars of the informed consents for students/parents
 - Sticker sheet with pseudonym (Pseudo-ID)

Participant Management documents T0-2

- prepare A4 envelope labelled **St-PM 3**:
 - Stick the Pseudo-ID on the envelope
- **Place in the envelope St-PM 3 the following:**
 - Consent form **after recorded in gPAS**
 - Contact information sheet for students (name, date of birth, home address, school and class)
 - A5 return envelope labelled "**St-PM 4**"

5.3. T1: Baseline survey

5.3.1. Preparation of study documents for students at T1

- Provide all required documents
 - Paper containing the QR-Code/Barcode for T1 (Awareness Questionnaire ECS T1) and the link to the Iodine feedback tool

Pseudonym Management T1

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Educational Setting" (study regions that only have one study design will only have their study design displayed)

- Select “Participants”
- Place the cursor in the field “Pseudonym”
- Use a QR/barcode scanner to scan the barcode of the declaration of consent and store it in the input field “pseudonym” in gPAS
- Place the cursor in the respective fields of the Questionnaires for T1 and scan the ID

Data Management documents T1

- Prepare 1 A4 envelope labelled **St-DM 1**
 - Write the name of the student on the envelope
- **Place in the envelope St-DM 1 the following:**
- Paper containing the QR-Code/Barcode for T1 (Awareness Questionnaire ECS T1) and the link to the Iodine feedback tool
- The study site can decide whether the envelopes **St-DM 1** is handed over personally or sent to the schools by post.

5.4. T2: Follow-Up (2-4 weeks after baseline)

5.4.1. Preparation of study documents for students at T2

- Provide all required documents
 - Paper containing the QR-Code/Barcode for T2 (Awareness Questionnaire ECS T2)

Pseudonym Management T2

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select “Participants”
- Place the cursor in the field “Pseudonym” and scan the Pseudo-ID
- Place the cursor in the respective fields of the Questionnaire for T2 and scan the ID

Data Management documents T2

- Prepare 1 A4 envelope labelled **St-DM3**
 - Write the name of the student on the envelope
- **Place in the envelope St-DM3 the following:**
 - Paper containing the QR-Code/Barcode for T2 (Awareness Questionnaire ECS T2)
- The envelopes **St-DM3** are handed over personally.

5.5. T0-3: Process evaluation

5.5.1. Preparation of study documents for teachers at T0-3

- Provide all required documents

- Paper containing the QR-Code/Barcode for T0-3 (Process Evaluation Questionnaire ECS T0-3)

Pseudonym Management T0-3

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Teachers"
- 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 T0-3 and scan the ID

Data Management documents T0-3

- Prepare 1 A4 envelope labelled **T-DM3**
 - Stick Pseudo-ID on envelope
 - Write the name of the teacher on the envelope
- **Place in the envelope T-DM3 the following:**
 - Paper containing the QR-Code/Barcode for T0-3 (Awareness Questionnaire ECS T0-3)
- The study site can decide whether the envelopes **T-DM3** is handed over personally or sent to the schools by post.

5.6. T0-4: Process evaluation interview (only subgroup of teachers)

5.6.1. Preparation of interview materials for teachers at T0-4

Regional Management will interview **two teachers**. For this sub-sample this equipment will be provided: ID for Interview file (only if teacher was chosen for interview)

- Topic guide for interview with guidelines (only if teacher was chosen for interview)
- Audio-recording device and ID for interview file (only if teacher was chosen for interview)
- A4 return envelope labelled **T-DM6** (only if teacher was chosen for interview)

Pseudonym Management T0-4

- Open web surface of Pseudonym Management System (gPAS)
- Select study "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Teachers"
- Place the cursor in the field "Pseudonym" and scan the Pseudo-ID
- Place the cursor in the respective fields of the "Interview" and scan the ID

Data Management documents T0-4

- Prepare one A4 envelope labelled **T-DM5**
 - Stick Pseudo-ID on envelope
 - Write the name of the teacher on the envelope
- **Place in the envelope T-DM5 the following:**
 - ID for interview file (only if teacher was chosen for interview)
 - Topic guide for interview with guidelines (only if teacher was chosen for interview)
 - Audio-recording device and ID for interview file (only if teacher was chosen for interview)
 - A4 return envelope labelled **T-DM6** (only if teacher was chosen for interview)
- The envelopes **T-DM5** are handed over personally (could be combined with **T-DM3** from T0-3)

5.7. T3: Follow-Up (6-8 months after baseline)

5.7.1. Preparation of study documents for students at T3

- provide all required documents
 - Sticker sheet with Pseudonym (Pseudo-ID)
 - Paper containing the QR-Code/Barcode for T-3 ([Awareness Questionnaire ECS T-3](#))

Pseudonym Management T3

- Open web surface of Pseudonym Management System (gPAS)
- Select study design "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Participants"
- Place the cursor in the field "Pseudonym" and scan the Pseudo-ID
- Place the cursor in the respective fields of the Questionnaire for T3 and scan the ID

Data Management documents T3

- Prepare 1 A4 envelope labelled **St-DM 5**
 - Stick Pseudo-ID on envelope
 - Write the name of the student on the envelope
- **Place in the envelope St-DM5 the following:**
 - Paper containing the QR-Code/Barcode for T0-3 ([Awareness Questionnaire ECS T-3](#))
 - ID for Interview file
- The study site can decide whether the envelopes **St-DM 5** is handed over personally or sent to the schools by post.

5.8. T3: Process evaluation interview (only subgroup of students)

5.8.1. Preparation of interview materials for students at T-3

Regional Management will interview **four students**. For this sub-sample this equipment will be provided: ID for Interview file (only if student was chosen for interview)

- Topic guide for interview with guidelines (only if student was chosen for interview)
- Audio-recording device and ID for interview file only if student was chosen for interview)
- A4 return envelope labelled **ST-DM8** (only if student was chosen for interview)

Pseudonym Management T-3

- Open web surface of Pseudonym Management System (gPAS)
- Select study "Educational Setting" (study regions that only have one study design will only have their study design displayed)
- Select "Participants"
- Place the cursor in the field "Pseudonym" and scan the Pseudo-ID
- Place the cursor in the respective fields of the "Interview" and scan the ID

Data Management documents T-3

- Prepare one A4 envelope labelled **ST-DM7**
 - Stick Pseudo-ID on envelope
 - Write the name of the student on the envelope
- **Place in the envelope ST-DM7 the following:**
 - ID for interview file (only if teacher was chosen for interview)
 - Topic guide for interview with guidelines (only if teacher was chosen for interview)
 - Audio-recording device and ID for interview file (only if teacher was chosen for interview)
 - A4 return envelope labelled **ST-DM8** (only if teacher was chosen for interview)
- The envelopes **ST-DM7** are handed over personally (could be combined with **ST-DM5** from T-3)

6. Handling at the school site

6.1.1. T0-1: Informed Consents and contact information from teachers

- A member of the Regional Management will open the A4 envelope labelled **T-PM 1** and collect the contact data and informed consent as described in the SOP "Informed Consents and Revocations". The teacher will receive a copy (digital or printed)
- Appointments are set for the data collection (ideally for all time points)

- *If no follow-up appointments can be made at T0-1, the Participant Management team will contact the teacher at least 3 days before the end of the period to arrange an appointment.*
- Contact data sheet is then placed in the A5 envelope labelled **T-PM 2** and sealed.
- The envelope **T-PM 2** be collected by a member of the study Regional Management or sent by post.

6.1.2. T0-2: Informed Consents from students and/or parents

- A member of the Regional Management or a trained teacher will open the A4 envelope labelled **St-PM3** and collect the informed consent as described in the SOP “Informed Consents and Revocations”. The student and/or parent will receive a copy.
- The second signed copy of the consent form is then placed in the A5 envelope labelled **St-PM 4** and sealed.
- The envelope **St-PM 4** be collected by a member of the study Regional Management or sent by post.

6.1.3. T1: Questionnaire from students

- The teacher will open the A4 envelope labelled **St-DM1** and hand over the letter with the access code to the questionnaire for T1 in LimeSurvey.
- The teacher decides when the Iodine feedback tool will be used. But it should not be used before the Awareness Questionnaire was filled the first time.

6.1.4. T2: Questionnaire from students

- The teacher will distribute the envelopes **St-DM3** to the addressed students.
- The students will open the envelope and complete the questionnaire for T2 online in LimeSurvey.

6.1.5. T0-3: Process evaluation

- The teacher will open the A4 envelope labelled **T-DM3** and complete the Questionnaire for T0-3 online in LimeSurvey.

6.1.6. T0-4: Process evaluation interview (only subgroup of teachers)

- Teachers chosen for interview will be the interview file ID from **T-DM5** to the interview room.
- Teachers are interviewed by a member of the Regional Management. The Regional Management is not allowed to know the name of the teacher.
- The interview will be audiotaped
- The audio file will be labelled/named with the interview ID.
- The interview file is then placed in the A4 envelope labelled **T-DM6** and sealed. **No name should be written on the questionnaires or the envelope labelled T-DM6.**
- The staff of the Regional Management will collect the envelopes **T-DM6**.

6.1.7. T3: Questionnaire for students and Interviews (only subgroup of students)

- A member of the Regional Management will come to the school and hand over the envelopes **St-DM5** to the teacher.
- The member of the Regional Management will take the audio recording device and wait in the room where the interview will be conducted.
- The teacher will distribute the envelopes labelled **St-DM5** to the addressed students.
- The students will open the envelope and complete the Questionnaire for T3 online in LimeSurvey.
- Students chosen for Interview will bring the Interview file ID from the envelope **St-DM7** to the interview room.
- Students are interviewed by a member of the Regional Management. The Regional Management is not allowed to know the name of the student.
- The interview will be audiotaped.
- The audio file will be labelled/named with the interview ID.
- The Interview files (if student was chosen for Interview) are then placed in the A4 envelope labelled **St-DM8** and sealed. **No name should be written on the envelope labelled St-DM8.**
- The staff of the Regional Management will collect the envelope **St-DM8**.

7. Handling at the Regional Management

7.1. Data for Participant Management

- The **T-PM 1** and **ST- 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 teachers 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 paper copy of the informed consents is then kept as backup 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. Data for Data Management

Professional Transcription of Interviews

- The **T-DM6** and **St-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.