



Informed consent form for the participation in the EUthyroid2 study

Dear healthcare professional,

Thank you for taking part in the EUthyroid2 project and providing the participating young women with information on iodine or helping with the recruitment of young women for the study.

As you are part of the team delivering the study in your country, you have gathered experiences on the implementation process or on educating the young women who participate in the intervention.

At the end of the EUthyroid2 project, we want to evaluate if the intervention improved young women's (18-24 years old) understanding of iodine and iodine deficiency-related disorders. For this, young women are being surveyed, and some women are also interviewed on their experiences during the study. Similarly, to evaluate the implementation of the study, we would like to survey and/or interview healthcare professionals on their experiences in the study. This knowledge helps us understand what makes the intervention effective and what processes are helpful for the implementation of the intervention.

By participating in the EUthyroid2 surveys and/or interviews you can support the research team find best-practice models to increase knowledge and awareness of iodine and iodine-related diseases.

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will receive a copy of the full Informed Consent Form. Please note that taking part in the study is entirely voluntary. You can revoke this consent in writing or verbally at any time without giving reasons and without incurring any disadvantages (see more details in the section: "Voluntary Participation").

Study Coordination:

University Medicine Greifswald
Institute for Community Medicine
Department SHIP/Clinical
Epidemiological Research
Prof. Henry Völzke, MD
Walther Rathenau Str. 48
17475 Greifswald
Germany

Regional Management:

Bangladesh University of Health Sciences
Faculty of Public Health
Department of Noncommunicable Diseases
Prof. Dr. Faridul Alam
125/1 Darus Salam, Mirpur-1
Dhaka 1216
Bangladesh

Part I:

Information Sheet

We would like to give you information on the EUthyroid2 project and invite you to participate in the study. Read through the following information carefully, and feel free to discuss it with colleagues, family members, or friends. If you have any questions or you would like more detailed information before deciding to participate, please contact the regional management whose details are included on the front page.

The EUthyroid2 project

The EUthyroid2 project is funded by the European Union and the UK Research and Innovation as part of the Horizon Europe Framework Programme to reduce the risk of non-communicable diseases in adolescents and young people. The four-year project is divided into two sub-studies taking place in the educational and healthcare settings of six European countries (the Republic of Cyprus, England, Northern Ireland, Norway, Poland and Slovenia) and two non-European countries (Bangladesh and Pakistan). The aim of the sub-study in the healthcare setting, which we would like you to participate in, is to improve young women's (18-24 years old) understanding of iodine and iodine deficiency-related disorders. For this, we need to know what knowledge on iodine and iodine deficiency-related disorders young women have and what their nutritional habits are.

Women who wish to participate in the study receive information in different forms. They will have the opportunity to fill out a self-assessment tool on their personal intake of iodine sources. Furthermore, a healthcare professional will educate them on iodine, will provide further information materials, for instance a factsheet or will give access to a link/QR code to a video on iodine. Should they have more questions on the topic of iodine, a contact person will be provided.

The participating young women will be asked to fill out questionnaires on their nutritional habits and their knowledge on iodine. Furthermore, they will be asked to give a urinary sample that can be used to analyse their iodine level. These measurements (the questionnaires and the urinary sample) will be

conducted three times: at the beginning (when they decide to participate), after 2-4 weeks and then, after 26-35 weeks.

The healthcare professionals who will deliver the intervention in the respective countries will be asked to participate in the surveys or in an interview. The surveys will be conducted three times: at the beginning of the study (before they are educated on the study procedures and intervention), after being educated, and at the end of the implementation. They will be asked about their knowledge on iodine, their opinion on the intervention materials, and their experiences during the study period. The interview will focus on personal experiences and opinions on the implementation process.

By participating in the surveys and/or the interview, you can contribute to find best-practice models and increase knowledge and awareness of iodine and iodine-related diseases in your country.

Voluntary Participation

It is entirely your voluntary decision whether or not to take part in the study. If you decide to take part, you will be asked to sign a consent form. You will be given a copy of the participant information sheet and consent form. You can revoke this consent in writing or verbally at any time without giving reasons and without incurring any disadvantages.

Procedures

If you agree to take part, you:

- will be asked to fill a questionnaire before and after being educated on the intervention and study procedures, as well as at the end of implementation
- may be contacted to be interviewed by a researcher of the EUthyroid2 team on your experiences in the study

Questionnaire

You will be asked to fill out a paper-based or online survey which will be prepared by the research team and provided by a healthcare professional (first measurement).

The questionnaire will include questions regarding your age, education, your knowledge on iodine, your nutritional habits, etc. The survey will be conducted pseudonymously which means that all information that could be used to identify you as a person will be replaced by a combination of 8 characters of lower case letters, upper case letters, and digits (see more details in the section: "Confidentiality").

The data will be transmitted in an encrypted form via a secure internet connection to a server operated by the University Medicine Greifswald, Germany. For the aim of the EUthyroid2 study, the data will only be processed and analysed by the EUthyroid2 research team who will not be able to see any personalised data, only the pseudonymised data. This means that it will not be possible to trace back the data to you individually (you can read more in the section: "Confidentiality").

Interview

A small sample of healthcare professionals will be contacted by a representative of the EUthyroid2 research team to ask if they want to participate in an approximately 30-60 minute long interview. The aim of the interview would be to gain insight into the healthcare professionals' experiences during the study and assess how well it is being conducted in practice. For example, this could include questions on your experiences about the recruitment process, your opinion on the information materials, or what you believe should have been done differently.

Should you agree to take part in the interview, the responsible researcher will carefully talk you through each part of the interview based on a prepared list of questions. If you do not wish to answer some questions during the interview, you may say so, and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. To be able to analyse conducted interviews, each interview needs to be audio recorded, and this would also apply to the interview with you if you decide to participate. The information recorded will be confidential, and no one else except the research team will have access to the information documented during your interview. Even though the entire interview will be recorded, the recorded file or the transcription of the audio file will not contain your name or other personal information that could lead to your identification. Similarly to the questionnaires, you will be allocated a pseudonym, for example a number that your audio file and the transcript will be identifiable with.

The audio file and the transcript will be transmitted in an encrypted form via a secure internet connection to a server operated by the University of Greifswald, Germany. The Heinrich Heine University of Düsseldorf, Germany is an official partner of the EUthyroid2 project and the involved researchers will perform the analyses of the interview data.

The audio file will be kept until the end of the study and will be deleted afterwards. The transcripts of the audio files will be used for data analysis after being translated into English, if applicable, and they will be stored for 10 years.

What are the possible disadvantages and risks of taking part in the study?

In all, there is no obvious reason why any problems should arise for you taking part in the surveys or interview, or that you may be harmed as a result of participating in the research.

If you have any complaint about the way you have been dealt with during the study, you should contact the Regional Management in the first instance, and Coordinator of the study in the second instance either by phone or by e-mail (see the first page with contact information).

What are the possible benefits of taking part in the study?

Within the study, you will have the opportunity to learn about iodine and iodine deficiency-related disorders. Your participation is likely to help us find out more about how to prevent iodine deficiency and iodine-related disorders in your country. EUthyroid2 aims to serve our societies by conducting research to improve public health. By participating in the study, you contribute to this aim.

Reimbursements

If you participate in the study, you will receive an expense allowance.

Confidentiality

All members of the project consortium are obliged to comply with the provisions of the European General Data Protection Regulation (GDPR) in the handling of personal data and are subject to the duty of confidentiality.

In case of personal data, we distinguish between personal contact data and collected study data. Personal contact data includes all the data that allow to identify you as a person: for example, first name/

last name, address, date of birth, and health insurance number. Study data includes all the answers of the questionnaires and the interview.

Your personal data (name and address) and the study data will be stored separately in terms of space and computer technology. The data collected during the interviews and examinations will not be stored with any name and address but will be coded with a number (so-called pseudonymisation). Only the management will have access to any personal data. All the scientific analyses will be carried out with pseudonymised data. The transmission of study data from the study centre to other scientific groups will also be pseudonymised. All the scientific publications will be anonymised and grouped: for example, in tabular and graphical form or with statistical measures (e.g. percentage, mean). Anonymisation will be achieved by deleting the assignment of the pseudonym to your personal contact data. Afterwards, the survey data can no longer be assigned to an individual person and no conclusions can be drawn about individual participants.

We would like to point out your rights with regard to your personal data. On the basis of the European General Data Protection Regulation (GDPR), you are entitled to the following rights, in particular:

Right of access (Art. 15 GDPR): you have the right to obtain information about the data stored about you.

Right to rectification (Art. 16 GDPR): you have the right to obtain rectification of any inaccurate personal data concerning you. Taking into account the purposes of the processing, you have the right to have incomplete personal data completed, including by means of providing a supplementary statement.

Right to erasure (Art. 17 GDPR): you have the right to obtain erasure of personal data concerning you if a certain ground for erasure applies. This is particularly the case if the personal data are no longer necessary in relation to the purposes for which they were collected or they were otherwise processed.

Right to restriction of processing (Art. 18 GDPR): you have the right to obtain restriction of processing. This means your personal data will not be processed with the exception of storage.

Withdrawal of consent (Art. 7 (3) GDPR): you have the right to withdraw your consent at any time.

Right to data portability (Art. 20 GDPR): you have the right to receive personal data concerning you in a structured, commonly used and machine-readable format. You have the right to have the personal data transmitted directly from one controller to another, where technically feasible.

Right to lodge a complaint with a supervisory authority (Art 77 GDPR): You have the right to lodge a complaint with a supervisory authority in the State of your habitual residence:

National Cyber Security Agency
E-14/X, ICT Tower (level-12), Agargaon, Dhaka-1207
E-mail: notify@dsa.gov.bd
(<https://www.dlapiperdataprotection.com/index.html?t=authority&c=BD>)

If you believe that the place of the alleged infringement is the University Medicine Greifswald, Germany, you have the right to lodge a complaint with:

The State Commissioner for Data Protection and Freedom of Information of Mecklenburg-Western Pomerania.

Schloss Schwerin
Lennéstraße 1
19053 Schwerin
Germany
Telefon: 0385-59494-0
Telefax: 0385-59494-58
E-Mail: info@datenschutz-mv.de

If you believe that the place of the alleged infringement is the Institute of Marine Research, Bergen, Norway, you have the right to lodge a complaint with:

Datatilsynet
Postboks 458 Sentrum
0105 Oslo
Norway
E-Mail: postkasse@datatilsynet.no

The data protection officer of the University Medicine Greifswald, Germany is:

Prof. Ulf Glende
Konzerndatenschutzbeauftragter
Informationssicherheitsbeauftragter
Universitätsmedizin Greifswald
Walther Rathenau Straße 48
17475 Greifswald
Telefon: 03834-865124
E-Mail: datenschutz-umg@med.uni-greifswald.de

The data protection officer of the Institute of Marine Research, Norway, Bergen can be contacted on:

personvernombud@hi.no

Address for withdrawal of consent:

Bangladesh University of Health Sciences (Regional Management)
125/1 Darus Salam, Mirpur-1, Dhaka
Email address: mithilafaruque@buhs.ac.bd

Entity responsible for data processing:

Department of NCD
Bangladesh University of Health Sciences, Dhaka

Who may use the study data and for what purpose?

The study data will be used by the members of the project consortium to make recommendations about how to improve young women's (18-24 years old) understanding of iodine and iodine deficiency-related disorders. Based on this, further scientific questions for public health and related disciplines can be generated for the general public. The data can also be used anonymously or pseudonymously with national and international cooperation partners, for example, from research. In addition, study data can be used in the context of education, training and continuing education.

How long will the data be stored and can you have the data deleted?

The raw data will be kept for 10 years after the completion of the study. You have the option at any time to revoke your consent to storage of the data partly or entirely in writing without giving reasons and without incurring any disadvantages. In the event of your revocation, your personal data (for example, your name or your address) will be deleted and your examination data will be made anonymous. From this point on, it is no longer possible to draw conclusions from the study data. Your study data cannot be deleted but will be blocked for future analyses if you wish.

Part II:

Certificate of Consent

I have read the foregoing information.

I have had the opportunity to ask questions about it and my questions have been answered.

I voluntarily consent to be a participant in the following procedures of the study:

Questionnaire	
<input type="radio"/> yes	<input type="radio"/> no
Interview	
<input type="radio"/> yes	<input type="radio"/> no
Comments:	
Date:	
Print name of participant:	
Signature:	

Statement by the person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the above consented procedures of the study will be done.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Date:	
Print name of the person taking the consent:	
Signature:	

Data protection

Declaration of consent under data protection law

A necessary prerequisite for participation in the study is your consent to data processing under the data protection law. Data processing includes, among other things, collection, storage, modification, usage and deletion of data.

I agree that my personal data will be processed under the responsibility of Bangladesh University of Health Sciences in cooperation with University Medicine Greifswald, as described in the information sheet.

yes no

I agree that my contact details (name, telephone number, email address) may be processed by the regional participant management. The participant management will not have access to the pseudonymised study data at any time.

yes no

I agree that my study data may be passed on and used in pseudonymised form as described in the information sheet to:

- the EUthyroid2 consortium and the international cooperation partners for research purposes (e.g. university facilities, research institutes).

yes no

Profit-related participation

I understand that I am not entitled to any compensation or other interest in any financial benefits, patents or profits that may be derived from research involving my data.

Right of withdrawal

Participation in the study is voluntary. I have the right to withdraw my consent in part or entirely at any time without giving reasons and without any disadvantages.

Re-contact

After your participation in the study, we may contact you again to recruit you to further studies within EUthyroid studies.

I agree to be contacted again by the research management as part of EUthyroid studies.

yes no

Date:

Print name of participant:

Signature:

