

CONSENT FORMS
for participation in a research programme

Title of the Programme you are invited to participate



HBM4EU-MOM

Development of fish consumption recommendations for healthy pregnancy
A harmonized pilot research study in five European countries

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This form provides the explanations in plain and` comprehensible language regarding what is being requested from you and/or what will happen to you if you agree to join the programme:

1. All risks that may exist or any inconvenience you may incur from participating in the programme.
2. The person(s) who will have access to your information and will arise from the programme you will take part in and/or other material/data that you voluntarily provide for the programme.
3. The time period during which the Principal Investigator will have access to your information and/or material concerning you.
4. What the Principal Investigator hope to learn as a result of your participation.
5. Estimation of the benefit that can be gained for researchers and/or sponsors of this programme.
6. **You should not participate if you do not wish to, or if you have any concerns about your participation in the programme.**
7. If you decide to join, you must indicate if you have participated in any other research programmes within the last 12 months.
8. If you decide not to participate and you are a patient, your treatment will not be affected by your decision.
9. **You are free to withdraw your consent to participating in the programme at any time.**
10. If you are a patient, your decision to withdraw your consent will not have any effect on your treatment.
11. All pages of consent forms must bear your full name and signature.

Principal Investigator of the Programme you are invited to participate in

Dr. (Ms.) Andromachi Katsonouri-Sazeides
 Head, Human Biomonitoring and Industrial Products Laboratory
 Cyprus State General Laboratory, Ministry of Health
 Visiting address: State General Laboratory - Annex II, Ippokratous 7, Akropolis, Nicosia
 Mailing Address: State General Laboratory, P.O. Box 28648, 2081 Nicosia, Cyprus
 Tel. +357-22-80-50-15, FAX +357-22-80-50-50,
 Email: akatsonouri@sgl.moh.gov.cy

Programme Duration:

October 2020 – December 2021

(An extension may be granted by the European Commission due to the COVID-19 pandemic)

Do you give consent for yourself or for someone else?

Surname:		Name:	
Signature:		Date:	

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If you have responded for another person, please provide details and name.

Question	YES or NO
Did you fill in your consent forms personally?	
Over the past 12 months, have you been involved in any other research programme?	
Did you read and understand the information regarding patients and/or volunteers?	
Have you had the opportunity to ask questions and discuss the Programme?	
Have you been given satisfactory answers and explanations to any of your questions?	
Do you understand that you can withdraw from the programme whenever you wish?	
Do you understand that if you withdraw, you do not need to give any explanations for your decision?	
(For patients) do you understand that, if you withdraw, there will be no impact on any treatment you get or you can get in the future?	
Do you agree to join the programme?	
With whom did you speak with?	

Brief description of the programme (procedures and purpose).

Healthy eating during pregnancy is very important for both the mother and her developing baby. A proper diet contributes to the best start to life by providing essential nutrients and by preventing potentially harmful toxins building up inside the mom's body.

You are invited to take part in the study HBM4EU-mom, a European policy support study aiming to develop simple fish-consumption recommendations for healthy pregnancy.

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Signature:		Date:	

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HBM4EU-mom runs in five European countries: Cyprus, Greece, Iceland, Portugal and Spain. It is coordinated by the Ministry of Health – State General Laboratory

You were randomly selected through your healthcare provider, to represent women in the first trimester of pregnancy, who live in Cyprus. If you agree to take part, you will be one of 130 women from Cyprus and one of 650 women from the whole of Europe to join this study. Taking part involves providing a small hair sample twice, answering the study's questionnaires, possibly receiving counselling about consuming fish during your pregnancy and keeping a simple record of the fish meals you are consuming.

Participation is entirely voluntary and it will not affect your medical care in any way. Your privacy and personal information will be strictly protected and you retain the right to withdraw from the study at any time, without any consequences. Your safety will always come first and all precautions will be taken to ensure that you are not at risk from COVID-19.

HBM4EU-mom is being done under the frame of a large partnership of 30 European countries, the European Environment Agency and the European Commission, called HBM4EU (Human Biomonitoring for Europe). It is co-funded by the European Commission and national governments. HBM4EU supports improved European policies for public health protection by generating new scientific data for the exposure of European citizens to environmental chemicals, including those coming from their diet. Both HBM4EU and HBM4EU-mom have been approved by the Cyprus National Bioethics Committee and complies with the European general data protection requirements.

The major goals of HBM4EU-mom are:

- to develop recommendations for fish consumption for healthy pregnancy
- to understand the current habits and needs of pregnant women regarding fish consumption in five coastal European countries - Cyprus, Greece, Iceland, Portugal and Spain
- to investigate the exposure of pregnant women to mercury
- to use the results of the study for supporting improved public health policies in Europe and to raise awareness of pregnant women and their health providers

Details of what will be requested and/or what will happen to programme participants

You consent to the following, by deciding to participate in *HBM4EU-mom*:

Surname:		Name:	
Signature:		Date:	

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- You agree to read the information provided to you so that you understand the purpose of the study, how it will be carried out, what your participation involves, your rights (to withdraw, to be forgotten, to choose whether you wish to be informed about your personal results) and your commitments.
- You agree to discuss and resolve any questions or concerns you may have about your participation with your healthcare provider or the National Study Leader of the *HBM4EU-mom* study and to sign this consent form only if you received satisfactory answers. The National Study Leader is:
Dr. Andromachi Katsonouri,
Head, Human Biomonitoring and Industrial Products Laboratory
Cyprus State General Laboratory, Ministry of Health
P.O. Box 28648, 2081 Nicosia, Cyprus
Tel. +357-22805015, FAX +357-22805050, Email: akatsonouri@sgl.moh.gov.cy
- You consent to provide two hair samples (just a few strands of hair from the back of the head, near the scalp, in a way which will not be disrupt your hairstyle). The first sample will be collected in the 1st trimester of pregnancy, during your normal visit to your healthcare provider. The second sample will be collected shortly before or after you give birth. Your samples will be coded so as to remove any information which can identify you and will be analysed to determine your exposure to mercury.
- You consent to be contacted by the research team for the purpose of the study and to answer the study questionnaires, so as to provide simple information about yourself, your health-status, lifestyle, occupation and diet - with special focus on fish consumption, which can help us to understand your results. The completion of the questionnaires will take place around the same time as the collection of your hair samples. You also consent to keep a simple log of the fish meals you consume during your participation in the HBM4EU-mom study.
- You consent to receive and follow the dietary recommendations provided to you by the research team, in relation to fish consumption during your pregnancy.
- You consent that the State General Laboratory of the Ministry of Health (National Study Leader) will have the access to your identifying personal information and will encode your data and samples according to the currently available safeguards, in such a way that other users of my data cannot trace back to you. The Data Protection Officer of the State General

Surname:		Name:	
Signature:		Date:	

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Laboratory is at your disposal for questions or concerns related to data protection and may be reached at the following contact information:

Dr. George Papageorgiou, Data Protection Officer
State General Laboratory of the Ministry of Health, Republic of Cyprus
Kyriakou Matsi Str., 1082 Nicosia
Tel.: +357 22809425, Fax: +357 22809455,
Email: gpapageorgiou@sgl.moh.gov.cy

- You consent to the storage and use of your coded hair samples and coded personal data collected in this study for research related to public health and environmental health purposes, even in the event of your death or your becoming incapacitated, for 10 years. After this period, your samples and data will be completely anonymized.
- You consent that your coded samples and/or data can be transferred to specialized laboratories, biobanks, databases, data infrastructures, research establishments, administrative authorities and institutions in the European Union and associated countries or used for public announcements and reports within the scope of the research.
- You consent that the State General Laboratory of the Ministry of Health may contact you in the future for public and environment health-related research purposes and/or to inform you about your personal results, if you choose to receive them. Please indicate your preference by marking your preference (please mark one option only):
 - ☐ I wish to receive my personal results
 - ☐ I wish to receive my personal results only if they exceed the health-based guidance values used in the study
 - ☐ I do not wish to receive my personal results.

Details of the funding of the research programme

HBM4EU - HBM4EU-mom is co-funded by the European Commission (Horizon 2020, Grant Agreement No. 733032) and the national governments of 30 European countries, including the Republic of Cyprus.

Details of any risks that may exist or any inconvenience that program participants may incur

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Signature:		Date:	

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Your participation in this study is not expected to cause you any risks greater than those encountered in everyday life.

To avoid any possible risk due to the COVID-19 pandemic, the hair samples will be collected by your health-care provider, who has been specially trained, and it will not affect your hair style. You can choose to complete the study questionnaires from the comfort of your home, by being interviewed by a trained fieldworker over the phone or in a teleconference.

Details of what information and/or what material will be collected under the programme, who will have access to it and for how long.

- You will provide a signed Consent Form, two hair samples, personal information (your lifestyle, educational level, occupation, your diet – with more detail on fish consumption) via the completion of the study questionnaires and a log of the fish meals you consume during your participation in the study. These materials will be stored at the State General Laboratory of the Ministry of Health.
- Your identity and participation will remain confidential and the research team is bound to confidentiality and impartiality statements.
- The National Study Leader will encode your data and samples so that processing of your samples and data cannot trace back to you. Your samples and data will be used only according to your informed consent in compliance with the European General Data Protection Regulation (GDPR). The released results of the study will not identify you in any way. Any information which identifies you (name, contact details) will be kept separately and under protective measures.
- All electronic and paper records will be protected from unauthorized access of your private information. Published reports of the study will not contain information that can be traced back to you.
- A part of your coded hair sample will be stored for 10 years at State General Laboratory of the Ministry of Health for possible use in future ethically approved studies.
- A part of your coded hair samples will be transferred to specialized laboratories in Spain (ISCIII) and / or Slovenia (JSI) to determine your exposure to mercury, according to a bilateral agreement between the State General Laboratory of the Ministry of Health and the specialized laboratory.

Surname:		Name:	
Signature:		Date:	

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- Coded data collected from you and other participants will be stored and used for research purposes for 10 years, and after that time, your data will be completely anonymized. In compliance with GDPR, data will be shared with the HBM4EU data repository and IPCHEM - the European Commission Information platform for Chemical Monitoring (<https://ipchem.jrc.ec.europa.eu/>).
- Your coded data will be analysed statistically together with the coded data of all other participants from Cyprus, Greece, Spain, Portugal and Iceland by authorized scientists in Spain (ISCIII) and Slovenia (JSI), according to bilateral “Data transfer agreements” signed between State General Laboratory of the Ministry of Health and the designated institutes.

WHERE APPLICABLE, FUTURE STORAGE AND USE OF BIOLOGICAL SAMPLES AND PERSONAL DATA:

Please note and sign either left or right

Except for the purposes of this programme that will last for 2 years,

I consent: ☐

Signature:

Except for the purposes of this study that will last for 2 years,

I do not consent: ☐

Signature:

that my biological samples (hair) and information, which shall be stored at the State General Laboratory of the Ministry of Health, Republic of Cyprus, **may be kept for 10 years and be used in future studies** upon authorization of the Cyprus National Bioethics Committee (CNBC), following the relevant application for renewal by the Principal Investigator of this Programme, I understand that matters of confidentiality will always be in force.

If new information that directly affects your health is discovered, would you like to be informed?

YES

☐

NO

☐

I CANNOT MAKE A DECISION NOW. PLEASE ASK AGAIN IF NEEDED

☐

Surname:

.....

Name:

.....

Signature:

.....

Date:

.....

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Details of what data will be generated for you within the programme, who will have access to them and for how long.

The following data will be generated:

- Your personal results of the level of mercury in your hair samples. You have the right to receive your results. If your exposure is higher than the health-guidance values of the World Health Organization, the personal information you will provide will be used to understand the reasons of the increased exposure and to provide you with recommendation on how you can decrease your exposure.
- The collective results from all participants in the five countries (Cyprus, Greece, Spain, Portugal, Iceland) will be used to draw overall conclusions about fish consumption guidelines for healthy pregnancies and will be provided to national and European authorities to support policy actions related to chemical management for public health protection. They will also be disseminated to other stakeholders, including the general public, healthcare providers of pregnant women in Europe, scientists and other interested parties.

The following institutes and responsible scientists will have access to the data of participants:

- The State General Laboratory of the Ministry of Health (Dr. Andromachi Katsonouri, akatsonouri@sgl.moh.gov.cy) will have access to the coded results of Cypriot participants for 10 years, after which all results will be completely anonymized.
- The Instituto de Salud Carlos III (ISCIII), Spain (Dr. Argelia Castano, castano@isciii.es) and the Jožef Stefan Institute (JSI), Slovenia (Dr. Milena Horvat, milena.horvat@ijs.si) will have access to the European database of the collective coded data until the completion or termination of the HBM4EU – HBM4EU-mom study, solely for the purpose of the statistical analysis.
- The Aristotle University of Thessaloniki (AUTH), Greece (Prof. Dimosthenis Sarigiannis, denis@eng.auth.gr) will have access to the European database of the collective coded data until the completion or termination of the HBM4EU – HBM4EU-mom study, solely for the purpose of computational modelling.
- The Vlaamse Instelling voor Technologisch Onderzoek (VITO), Belgium (Prof. Greet Schoeters, greet.schoeters@vito.be), will have access to the European database of the collective coded data for the purpose of data management, for a total of 10 years.

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In the frame compliant with the European General Data Protection Regulation, the data will be made available on the European Commission's Information Platform for Chemical Monitoring, IPChem (<https://ipchem.jrc.ec.europa.eu/>).

Expected benefit for participants

- You will receive general dietary advice from our dieticians for healthy pregnancy and lactation after giving birth
- You will have the right to receive your personal results (if you wish), which you may subsequently further examine with your doctor and to receive personalized guidance based on your results
- You and all citizens in Cyprus and in Europe will benefit from the collective results of the study, which will include
 - Simple, easy to follow recommendations for fish consumption during pregnancy, for improved health of the developing baby and the mother
 - New scientific data, which will be used to support policy decisions at national, European and possibly global level
 - Improved awareness by European pregnant women, their health-care providers and society at large

Expected benefit for researchers and/or sponsors

The sponsors of this study (European Commission and Republic of Cyprus) will benefit from the availability of new, reliable scientific data, which can inform better policies for public health protection and for the control of prenatal exposure to mercury, in particular.

The research team is expected to gain expertise and scientific recognition for the achievements of the study.

Details of termination or early postponement of the research programme.

The investigators retain the right to terminate or postpone the study without regard to the participant's consent, in the event that their ability to implement the study is compromised by factors beyond their power, such as by the COVID-19 pandemic.

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Signature:		Date:	

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Site and duration of storage of data and/or biological samples to be collected under the programme

Site of storage of samples and data containing personal information:

Human Biomonitoring and Industrial Products Laboratory
Cyprus State General Laboratory, Ministry of Health
P.O. Box 28648, 2081 Nicosia, Cyprus

Length of Storage of samples and data containing personal information: 10 years

Description of procedures of handling data and/or biological samples of participants who withdraw from the study prior to its completion.

You are free to withdraw from the study at any time, without any consequences, by signing the “Withdrawal Form” of the HBM4EU-mom study.

We will no longer contact you and will destroy your samples and data, unless they have been completely anonymized and we cannot trace them back to you. For the integrity of the study and in the interest of public health, we will retain your coded data in analyses that have already been completed. We will retain your signed consent and withdrawal forms as a record of your wishes and for audit purposes.

Full contact details and title of the person to whom participants can submit complaints or grievances regarding the programme they participate in.

Dr. Ioanna Gregoriou,
Medical Services and Public Health Services, Ministry of Health, Republic of Cyprus
Prodromou 1 / Chilonos 17, 1448 Nicosia
Tel. 22605300 / 301, Email: igregoriou@mphs.moh.gov.cy

Alternatively,

Dr. Anthi Vassiliadou,
Paediatric Clinic, Larnaka General Hospital, United States Str., 6301 Larnaka
Tel. 24800500, FAX. 24803298, Email: dr.vasileiadou@gmail.com

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Full contact details and title of the person whom participants can contact for more information or clarifications about the research programme.

You can contact your healthcare practitioner, who follows you during your pregnancy, or the coordinator and National Study Leader of the study, whose name and contact information are:

Dr. Andromachi Katsonouri,
Head, Human Biomonitoring and Industrial Products Laboratory
Cyprus State General Laboratory, Ministry of Health
P.O. Box 28648, 2081 Nicosia, Cyprus
Tel. +357-22805015, FAX +357-22805050
Email: akatsonouri@sgl.moh.gov.cy

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Signature:		Date:	