HBM4EU science and policy for a healthy future

REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

ΓΕΝΙΚΟ ΧΗΜΕΙΟ ΤΟΥ ΚΡΑΤΟΥΣ
ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
STATE GENERAL LABORATORY
REPUBLIC OF CYPRUS

PARTICIPANT Information Booklet

HBM4EU-MOM

Development of fish consumption recommendations for healthy pregnancy

A harmonized pilot research study in five European countries

Cocreating a healthier future for our children, together

Nicosia

2021


HBM4EU-MOM

HBM4EU-MOM

Invitation to join the HBM4EU-mom study: Development of fish-consumption recommendations for healthy pregnancy

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.

We invite you, as an expectant mom in your first trimester of pregnancy, to help us develop simple fish-consumption recommendations for healthy pregnancy by taking part in the research study *HBM4EU-mom*. By becoming part of our community of pregnant women, healthcare providers and scientists from across Europe, you can contribute to improved public health policies and a healthier start to lives of European children.

HBM4EU-mom runs in five European countries - Cyprus, Greece, Iceland, Portugal and Spain and it is coordinated by the Ministry of Health – State General Laboratory. It 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). HBM4EU supports improved European policies for public health protection, by generating new scientific data relevant to European citizens. Both HBM4EU and HBM4EU-mom have been approved by the Cyprus National Bioethics Committee.

Taking part involves providing a small hair sample (just a few strands, which will not be affecting your hairstyle) and answering the study's questionnaires during the first trimester of your pregnancy and shortly before or after giving birth to your baby. You may also be contacted by our research team to receive counselling about consuming fish during your pregnancy and to keep a simple record of the fish meals you are consuming. Your participation is voluntary, and you can opt out at any time without affecting the medical care you will receive.
By taking part, you can help us to understand the needs of pregnant women in Cyprus and in Europe, so that we can support healthier pregnancies through recommendations for fish consumption.

Your personal information and samples will be coded and pseudonymized to protect your privacy. You can find out more about the study by reading the enclosed leaflet, visiting https://www.hbm4eu.eu/ or talking to our research team, which includes your healthcare provider.

Do not hesitate to contact us should you have any concerns or wish to discuss further about this invitation.

Please inform your health-care provider about your decision to confirm or refuse participation.

Thank you for your time and for considering to participate in our efforts to co-create a healthier future for our children, through healthier dietary choices during pregnancy.

Yours sincerely,

Dr. Andromachi Katsonouri, Ph.D.
Principal Investigator at European Level and
National Study Leader in Cypurs
Head of Human Biomonitoring Laboratory, State General Laboratory, Ministry of Health, Republic of Cyprus

Dr. Afroditi Elisseou-Xenofontos, M.D.
Obstetrician/Gynaecologist, Mother & Child Clinic, Nicosia and
Clinical Assistant Professor at the University of Nicosia Medical School

Dr. Adamos Hadjipanayis, M.D., Ph.D.
President of the European Paediatric Association,
Head of Paediatric Clinic of the Larnaca General Hospital

Dr. Eleni Pipi, M.D.
Obstetrician/Gynaecologist, Mother & Child Clinic, Nicosia

Dr. Charis Kontos, M.D.
Obstetrician/Gynaecologist, Iasis Hospital, Paphos

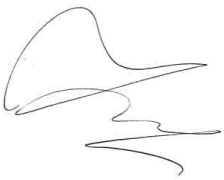
Dr. Renos Afxentiou, M.D.
Obstetrician/Gynaecologist, Afxention Medical Centre, Paralimni

Dr. Andri Kakkoura, M.D.
Obstetrician/Gynaecologist, Hippocrateon Private Hospital, Nicosia

Dr. Stavros Zarkadas, M.D., Ph.D., DMAS
Obstetrician/Gynaecologist, Larnaca

Dr. Kostas Flouris, M.D.
Obstetrician/Gynaecologist, Paralimni

Dr. Sofia Frakala, M.D.
Obstetrician/Gynaecologist, Nicosia



Dr. Zoe Ntontou, M.D.
Obstetrician/Gynaecologist, Nicosia

Dr. Niki Agathokleous, M.D.
Obstetrician/Gynaecologist, Limassol

Dr. Konstantinos Stylianides, M.D.
Obstetrician/Gynaecologist, Nicosia

Dr. Nikos Zottis, M.D.
Obstetrician/Gynaecologist, Nicosia

Dr. Anthi Pitta, M.D.
Obstetrician/Gynaecologist, Nicosia

HBM4EU-MOM

Information for Participants

HBM4EU-mom and its importance to you and to public health

HBM4EU-mom is a European policy support study, aiming to develop simple fish-consumption recommendations for healthy pregnancy and it is under the coordination of the Ministry of Health – State General Laboratory of the Republic of Cyprus.

HBM4EU-mom engages more than 650 pregnant European women from Cyprus, Greece, Iceland, Portugal and Spain, who are being randomly recruited through their health-care practitioners. It runs from October 2020 through December 2021. It is implemented in the frame of the European Human Biomonitoring Initiative, HBM4EU. HBM4EU is an innovative European Joint Program, which aims to understand people's exposure to chemicals and the related health risk by using **human biomonitoring** (measurements of environmental chemicals or their reaction products in biological samples collected from volunteering citizens). The results are being used, wherever appropriate, to support policy makers with their decisions regarding the safe management of chemicals and the protection of human health in Europe. By engaging with participants like you, HBM4EU helps to raise awareness among the public and promotes actions to prevent exposures to potentially harmful chemicals and to promote a healthier future for European citizens. HBM4EU is funded by the European Commission and national governments, runs from 2017 to 2021 and includes experts from 30 countries and European Union agencies. In Cyprus, HBM4EU is under the responsibility of the State General Laboratory of the Ministry of Health. You can learn more on our website: https://www.hbm4eu.eu/

Why is this study being done and who approved it?

The HBM4EU-mom study has been approved by the Cyprus National Bioethics Committee and complies with the European general data protection requirements[1].

The major goals of this study 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

Eligibility Criteria

You must fulfill the following criteria to be eligible to participate in this study:

- You live in Cyprus for the last 3 years and are fluent in Greek or English

[1] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, *OJ L 119, 4.5.2016, p. 1–88* (General Data Protection Regulation, "GDPR")

- You are 18-45 years old
- You are in good overall health, as assessed by your gynecologist / obstetrician
- You are pregnant with a single child, in the first trimester of your pregnancy
- You include or are willing to include fish in your diet
- You consent to be contacted by the research team for the purpose of the study, to provide a small hair sample and complete a questionnaire during the first trimester of your pregnancy and shortly before or after giving birth and to possibly receive and follow guidance on fish consumption during your pregnancy

If your participation is confirmed, your healthcare provider will ask you to complete and sign the enclosed consent form in duplicate, before or at the beginning of your appointment. You can ask any questions you wish and you can take the time you need to clarify any concerns prior to signing. You will keep one copy of the consent form for your records and we will keep the other for our records.

What if I don't want to participate?
It is entirely your choice and it will not affect your health care in any way.
If nonetheless, you are willing to answer a few optional questions completely anonymously, you can help us to understand how the people who choose not to take part in the study compare to the people who want to take part, which can help us to improve future studies.

Do I need any special preparations in order to participate?
No special preparation is necessary.

How will my participation be done?

Your participation is being done through your healthcare provider. During your regular appointment at your first trimester of pregnancy, you can provide your written consent to participate in the study, after asking any questions you may have and receiving answers. Your healthcare provider will then take your hair sample (a few hair strands at the back of the head, near the scalp, in a way that will not disrupt your hairstyle). You will also schedule an appointment with our research team, which will be done via teleconferencing at a time of your preference, to complete the study questionnaire.
During your pregnancy, you may be contacted by the research team to receive counseling about consuming fish during your pregnancy and to keep a simple record of the fish meals you are consuming. To avoid any risk from COVID-19, distant ways of communication will be employed.
Shortly before or after you give birth, your healthcare provider will take a second hair sample for repetition of the analysis and you will be asked to complete a short questionnaire.

What will happen to my samples, data and results?

Your samples and data will be used only according to your informed consent and in a way that protects your privacy according to the European regulation GDPR[1] and national requirements. The released results of the study will not identify you in any way.

A code will be assigned to you by the National Study Leader, who will then remove all personal identifiable information to protect your privacy and make it impossible to trace your data or samples back to you.

A small amount of your coded hair sample will be transferred to a specialized laboratory in Spain (and / or Slovenia) for analysis of your exposure to mercury. A small amount of your coded hair sample will

then be stored at State General Laboratory for 10 years for possible use in future ethically approved studies.

Coded data collected from you and other participants will be stored and used for research purposes and may be combined with other data from different sources. The sharing of data will be facilitated through dedicated data infrastructures and/or Information systems (such as IPCHEM, which is the European Commission Information platform for Chemical Monitoring[2]).

The overall results of the study 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, scientists and other interested parties.

How can I learn about the results of the study?

Unless you expressed a wish on your certificate of informed consent not to receive your personal results, you will be notified when your results are ready, around December of 2021, by your healthcare provider and / or *the National Study Leader.* Your personal report will include the levels of mercury in your hair samples, which you can review with us.

You will also be informed about the *collective* results of the study. These will be published as a study report and will be publicly available at https://www.hbm4eu.eu/.

How will my privacy be protected?

Your privacy is protected by complying with the requirements of the European General Data Protection Regulation. The State General Laboratory is responsible for the protection of your data against loss, unauthorized access /use, modification / disclosure or other misuse.

The Data Controller of the State General 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

All data processing will be done in such a way, that it is no longer possible to attribute your data to you without the use of additional information. Your name will be replaced by a code. 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. Third parties will not have access to your personal results, unless you consent to.

Why do you need my written consent?

Your written consent confirms that you volunteer to take part in the study after understanding what is required from you and what your rights are. You have the right to withdraw your participation without any consequence at any point (including any data or samples already provided, if they have not been completely anonymized and so impossible to be traced back to you) and the right to choose if you want to receive your individual results or not. You will also confirm that we can contact you in the future to

[2] https://ipchem.jrc.ec.europa.eu

tell you about your personal results or for historical, statistical or scientific purposes. A copy of the Certificate of Informed Consent, which you will be asked to complete and sign before taking part in the study, is attached to this booklet and you can keep it for future reference.

How will I benefit if I participate?

- 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

Are there any risks if I join the HBM4EU study?

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 healthcare 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.

Are there any costs to me?

No, the study will be conducted at no cost to you. Participation is voluntary, without reimbursement.

What if I have any concerns or complaints while I am taking part in the study?

Your wellbeing is our foremost priority and we will take all necessary precautions to ensure your comfort and safety. If you have any concerns during your appointment, please discuss them with your healthcare provider. You can also contact the National Study Leader. You have the right to opt out of the study at any time and for any reason (without the need to disclose this).

In the unlikely event that you want to file a complaint about the study, you may do so by contacting either of the following doctors, who are not formally connected to the study and serve as independent overseers of its implementation:

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

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

What happens if I say yes, but I change my mind later?
You are free to withdraw from the study at any time, without any consequences by informing your healthcare provider or the National Study Leader. We will ask you to confirm your wishes by signing the attached withdrawal form. On this form you can indicate one of the following options:

- "No further contact but my samples and data can be used".
  We will no longer contact you, but have your permission to retain and use information and samples that you have already provided.
- "No further contact and my samples and data cannot be used".
  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.

You can request a copy of these forms by contacting the National Study Leader.

Who do I contact if I have any questions or would like further information about the study?
You can contact the **National Study Leader**:

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 can also visit our website, https://www.hbm4eu.eu/.

Thank you for your time and consideration!

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

CONSENT FORMS
for participation in a research programme

(The forms are comprised of 11 pages)

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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

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

CONSENT FORMS
for participation in a research programme
(The forms are comprised of 11 pages)

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

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?	
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?	

.....

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

CONSENT FORMS
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Title of the Programme you are invited to participate

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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. 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

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

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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

- 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*:

- 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

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

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 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.

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

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A harmonized pilot research study in five European countries

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
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.

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

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- 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.
- 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.

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

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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
☐	☐	☐

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 pregnanciesand 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

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

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.

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.

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

CONSENT FORMS
for participation in a research programme
(The forms are comprised of 11 pages)

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

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.

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

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

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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

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

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

Surname:	.....	Name:	.....
Signature:	.....	Date:	.....

HBM4EU-MOM

HBM4EU-MOM

Participant Withdrawal Form

Dear Participant,

you can withdraw from the HBM4EU-mom study at any time and without disclosing your reasons, by completing and signing this form. The form can be completed by you or by someone who is able to act on your behalf. Your signed consent and withdrawal forms will be kept by the State General Laboratory of the Ministry of Health as a record of your wishes. The options available to you for withdrawal are shown. Please indicate your preference by marking the appropriate box and adding your initials.

I wish to withdraw from the HBM4EU study and request:	Initials
☐ NO FURTHER CONTACT BUT MY CODED[1] SAMPLES AND INFORMATION CAN BE USED I will no longer be contacted but give my permission to the State General Laboratory of the Ministry of Health to retain and use information and samples already provided by me.	
☐ NO FURTHER CONTACT AND MY SAMPLES AND INFORMATION CANNOT BE USED I will no longer be contacted by the State General Laboratory of the Ministry of Health and the information and samples I already provided cannot be used for further analyses. My samples will be destroyed, but I understand that it may not be possible to trace all distributed samples remnants. I understand that it is not possible to remove coded data originating from me from analyses that have already been completed. The State General Laboratory will only hold my information for audit purposes.	

[1] The term "coded" means that my name has been replaced by a code, in order to protect my personal data.

On behalf of the participant withdrawing from the HBM4EU study:

_____	_____	_____
Location and date	Name of participant	Signature of participant or Name and signature of designated representative

On behalf of the State General Laboratory of the Ministry of Health:

_____	_____	_____
Location and date	Name of HBM4EU staff	Signature of HBM4EU staff

For internal use only:
Participant Code

HBM4EU-MOM

HBM4EU-MOM

NON-RESPONDERS QUESTIONNAIRE

To be filled by women who considered participating in the study but refused the invitation

INSTRUCTIONS
Thank you for taking the time to consider the information for participants in this study.
Please help us understand how the people who choose not to take part in the study compare to the people who want to take part, by answering the following questions. Your anonymous answers will be used strictly for this and audit purposes and to improve future studies.
Mark all that apply. If you feel uncomfortable answering a particular question, you may skip it.
Please return this form to your healthcare provider through whom the recruitment is being done

1. My age is:

☐ 18 - 25 ☐ 25 - 30 ☐ 30 – 35 ☐ above 35

2. My current work status is:

☐employed

☐unemployed. Please specify:

☐ family care / housekeeping ☐ looking for work ☐ unable to work

☐ studying ☐ other

3. My highest level of education is:

☐ elementary ☐ high school ☐ undergraduate ☐ graduate / professional

4. ☐ I'm in good health ☐ I have health problems

5. The frequency at which I eat fish is:

☐ never ☐ less than once per month ☐ 1-3 times per month

☐ once per week ☐ 2-4 times per week ☐ more than 5-6 times per week

6. ☐ I smoke ☐ I don't smoke

7. I do not wish to participate in this study because (Please check all that apply)

☐ I don't have time

☐ I don't like what I would need to do

☐ I don't see a value for society

☐ I am afraid to participate due to COVID-19

☐ I am not interested in the subject

☐ I don't see a value for me

☐ I don't like / trust the study organizers

☐ Other. Please specify:

……

HBM4EU-MOM

Partner Institutes

REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

ΓΕΝΙΚΟ ΧΗΜΕΙΟ ΤΟΥ ΚΡΑΤΟΥΣ
ΚΥΠΡΙΑΚΗ ΔΗΜΟΚΡΑΤΙΑ
STATE GENERAL LABORATORY
REPUBLIC OF CYPRUS

ARISTOTLE UNIVERSITY OF THESSALONIKI

UNIVERSITY OF ICELAND

REPÚBLICA PORTUGUESA
SAÚDE

Instituto Nacional de Saúde
Doutor Ricardo Jorge

GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA E INNOVACIÓN

Instituto de Salud Carlos III

Jožef Stefan Institute
Ljubljana, Slovenia

European Environment Agency

Umwelt Bundesamt

vito