

## Information for participants

### Could your *microbiome* predict a healthy pregnancy and delivery?

*The microbiome refers to the community of all bacteria, viruses and other micro-organisms residing at the different locations of your body, of which many are believed to have a beneficial effect on your health.*

With this large project we would like to explore how the **microbiome** during pregnancy is related to pregnancy-related medical problems in expecting mothers and their babies, to hopefully be able to detect, prevent and treat these in the (near) future. Therefore, we would like your help and invite you to participate if:

- You are older than 18 years and you are before your 19<sup>th</sup> week of pregnancy
- You are not participating in any other clinical studies involving medication intake during pregnancy
- You are residing in Sweden, and you have a personal identification number ("personnummer") and postal address in Sweden (to send the home-sampling kits)
- You are sufficiently fluent in Swedish or English to complete our web-based questionnaires

Most pregnancies proceed without any major problems and lead to a normal delivery with healthy babies. Complications in the mother and child are uncommon but do occur, for example preterm birth (when the baby is born before 37 weeks) occurs in approximately 5% of all pregnancies. Yet, it is still hard to predict which women are at risk for complications. We therefore want to examine if the microbiome could be a way to measure health and predict possible pregnancy-related complications in expecting mothers and their children, for example pre-term birth.

It is only during the last years that researchers have been able to map bacteria residing in the human body, and some smaller studies suggest that the bacteria can give us important information about our health. We now want to study this in more detail during pregnancy and therefore we would like your help.

**Since we want to reach as many pregnant women as possible and plan to recruit and follow-up 2500 women all over Sweden, you can participate completely from home, without any need for medical check-ups or additional trips to your antenatal clinic or elsewhere.**

We would like you to fill in a web-based **questionnaire** including among others, questions regarding your general health, your pregnancy, and dietary habits at three time points during your pregnancy: around week 17-19; around week 28-30, and 6-10 weeks after your expected delivery date. A few days after you have completed each questionnaire, you will **receive an envelope at home including a self-sampling kit** with instructions, so you can take the required samples yourself and send them back to our laboratory by mail with the enclosed pre-paid envelope (within one week after receiving the kit) for the analyses.

We would like you to collect samples at different body sites: your mouth (saliva), your vagina (soft swab), and your rectum (stool sample), which takes 5-10 minutes in total. With a soft sampling swab, you brush a little around the mucous membrane of the vagina, collect a little

**To participate in the project go to our website: [www.swemami.se](http://www.swemami.se) for more information and complete the questionnaire!**

stool in a test tube or spit saliva in a test tube. At the last time-point, we will also ask you to collect a stool sample from your baby (from the diaper) if you approve. So you will have to answer a questionnaire three times, and self-sample three times.

All sampling procedure are without any known health risk to your or your child, and are not painful but could lead to some minor and temporary discomfort.

When the study is finished we will analyse the bacteria and other microorganisms in your samples, and compare these with the other participating women (with or without pregnancy-related complications), and see if diet, drug intake and other factors may have an influence on the composition of your microbiome.

We also ask your permission to retrieve your **pregnancy-related medical records**, and to retrieve your data from the **National Health Registries**. The Swedish Health Registries contain information on every individual, which are linked with the personal identification number, for example on prescribed drug use, diseases and pregnancies. With your permission, we want to link information from the health registry with your medical (delivery) records, your sampled microbiome and the prescribed drugs you have used, and relevant information about your pregnancy and delivery. In addition, we would like to have your permission to collect the data of your child from the Health Registries, to see if there is any long-term association between your microbiome during pregnancy and early-childhood diseases (incl. epilepsy, allergy, autism, diabetes type I). This enables us to assess the health of your child up to the age of 10, without the need to contact you or your family again for additional examinations.

**Handling of data:** All collected data and samples will be coded, so identifiable data will only be used to obtain the questionnaire and registry data and will be stored separately (only accessible by those few researchers at our centre involved in this step of the project). All biological samples will be processed and stored in freezers at our centre at Karolinska Institutet in Stockholm as part of the Karolinska Institutet Biobank (contact Senior Lab Manager, Marica Hamsten, 08 524 853 08), and only be handled by our team of researchers. All samples will be coded and cannot be traced to any individual without access to the code key. All information will be processed confidentially, and be anonymised, and the samples will only be used for the purpose as described above. Results will only be presented in aggregated form. In case we would like to use your samples for other yet unforeseen research purposes in the future, we will apply for new ethics approval, and contact you again for your approval if needed. Karolinska Institutet is responsible for the data. According to the Swedish Personal Data Act (PuL) you have the right to once a year see the data about yourself and if necessary correct any errors.

It is completely voluntary to participate in the study and you can discontinue at any time. If you discontinue your participation this will not affect your healthcare in any way. If you wish to get more information about our project please contact us, or visit our website!

We wish you a wonderful pregnancy!

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