

MUMMIBODIES. EATING DISORDERS, PREGNANCY AND  
POSTPARTUM.

1 st of May 2020. VERSION 3.

VILA SULT  
INSTITUTT FOR  
SPISEFORSTYRRELSER



Norske Kvinners Sanitetsforening

# INVITATION TO PARTICIPATE IN A RESEARCH PROJECT

MUMMIBODIES. EATING DISORDERS, PREGNANCY  
AND POSTPARTUM.

## INFORMED CONSENT FORM (ICF)

Approved by REGIONAL COMMITTEES FOR  
MEDICAL AND HEALTH RESEARCH ETHICS  
(REC) 20<sup>th</sup> of May 2020, Reference 92665

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You are invited to participate in a research project “Mummibodies” to find out more on how pregnancy and labortime is experienced for women with eating disorders.

## **Why study this?**

This is a question for you to participate in a research project. The investigators would like to understand more about how women who struggle with food, body and weight experience being pregnant and having children. The investigators want to hear about your thoughts and experiences. More knowledge is important to be able to understand and help those who struggle with food, body and weight in an important phase of life. The investigators will find out more about thoughts and feelings women who struggle with eating disorders may have when they are pregnant and / or have had children. You will receive written information about the project before, during and after you have participated.

## **What does the study involve?**

Those who are invited to join are women who struggle with eating disorders while they are pregnant and after recently given birth. The investigators will talk to the informants during pregnancy and then again when the baby is born. The investigators are interested in hearing how the pregnancy is and how the time the first year of the baby's life has been.

If you want to join the study, we will first ask you to fill out a questionnaire about the symptoms of eating disorders. We do this to find out if you are suitable to participate in the study. If it turns out that your symptoms match a diagnosis of eating disorders, we invite you to participate in the study. If you say yes, psychologist Bente Sommerfeldt will do a clinical interview with you so that we can make a precise diagnosis. Then psychologist Bente Sommerfeldt will talk to you about what it is or was like to be pregnant, give birth and have children. Bente is a psychologist specialist and has many years of experience in the treatment of eating disorders. It will all take around three hours. But we divide it up so it will not be so tiring.

## **Foreseeable benefits and predictable risks and burdens of taking part**

What you say can help others who are struggling with eating disorders when they are pregnant or having children. It will also be able to help professionals become better at dealing with this type of problem. And, it could help create better deals for women in this often vulnerable phase of life.

For you, the survey provides an opportunity to air thoughts and feelings that you may not be talking to so many others about. You can do this to a neutral person who is only there to hear what you have to say and who you should have no relationship with. The conversations can make you more aware and reflective on your own situation and what can help you.

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However, filling out the form and the interview takes some time. Not everyone who initially wanted to join can join; they must have an eating disorder diagnosis as we consider it. Some may find it sensitive or challenging to talk about their own private thoughts and feelings to a stranger. Experiential conversations about difficult experiences in life can remind you of difficult thoughts and feelings that you have not thought about for a while. Our experience is that the participants tend to be happy that they have been involved in this type of project.

## **Voluntary participation and the possibility to withdraw consent**

Participation in the project is voluntary. If you wish to take part, you will need to sign the declaration of consent on the last page. You can, at any given time and without reason withdraw your consent. *You can delete this last sentence if the participant is not recruited by virtue of being a patient.* If you decide to withdraw participation in the project, you can demand that your tests and personal data concerning health be deleted, unless however, the personal data concerning health and tests have already been analysed or used in scientific publications. If you at a later point, wish to withdraw consent or have questions regarding the project, you can contact project manager Bente Sommerfeldt, 93221280 or bsommerfeldt@gmail.com.

**What will happen to your personal data concerning health?** Project leader professor, Arne Holte and PhD Student Bente Sommerfeldt, who has access to the health information, has a statutory duty of confidentiality. Both Arne and Bente have, of course, a duty of confidentiality both according to the psychologists' association's rules, the Health Personnel Act and the Penal Code. This means that they must prevent others from gaining access or knowledge of the information. However, the duty of confidentiality does not prevent you as a research participant from knowing what health information has been collected about you.

Any personal data concerning health that has been recorded about you will only be used as described in the purpose of the project. You have the right to access information that has been recorded about you and the right to stipulate that any error(s) in the information that is recorded is/are corrected. You also have the right to know which security measures have been/will be taken when your personal data concerning health is processed.

The information will be stored in a locked burglar-proof safe in Villa Sult. We will make audio recordings of the conversations. You have the right to hear the audio recording and you can demand that the recording be deleted at any time. All information about you will be processed without name and birth number or other directly recognizable information. A code links you to your information through a list of names. Only project manager Arne Holte and PhD Student Bente Sommerfeldt have access to this list. In 2023, the code list will be linked to a link key for five years for control purposes only. The code list is deleted and the material is destroyed in 2028, so that the data cannot be traced back to you.

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## **Insurance**

The survey is carried out under the auspices of the «Foundation Institute for Eating Disorders» and as a participant you are insured by the Norwegian Patient Injury Compensation.

## **Approval**

The Regional Committee for Medical and Health Research Ethics has reviewed and approved the Research Project, ref. 92665 (2020/2025).

In accordance with the General Data Protection Regulation the controller University of Oslo, Norway and the project manager Arne Holte/Bente Sommerfeldt is independently responsible to ensure that the processing of your personal data concerning health has a legal basis. This project has legal basis in accordance with the EUs General Data Protection Regulation, article 6 no. 1a, article 9 no. 2a and your consent.

You have the right to submit a complaint on the processing of your personal health data concerning health to the Norwegian Data Inspectorate (Datatilsynet).

## **Contact information**

If you have any questions regarding the project, you can contact psychologist specialist Bente Sommerfeldt, 93221280, bente@villasult.no. The privacy representative at the institution is astrid@villasult.no. If help and follow-up is desired, we ask you to send an email to post@spiseforstyrrelser.no. Mark the email with "Mummiebodies". You will be offered an hour within two weeks at the latest with one of Villa SULT's specialists.

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**I CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT AND THAT  
MY PERSONAL DATA CONCERNING HEALTH MATERIAL CAN BE USED  
AS DESCRIBED ABOVE**

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Place and date

Participant's signature

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Participants name (IN BLOCK LETTERS)