

Amsterdam, November 2021

Information on donating fetal remains for scientific research

Dear Madam, Sir,

With this information letter, we would like to inform you about the option to donate your child to science for medical research, for which we ask your cooperation and that of your partner.

We understand that this is a difficult time to be asked to participate in a study. We would like to stress that participation is completely voluntary. If you consent to participate, your child will not be cremated or buried, but donated to science. The aim of the scientific study is to better understand development of unborn children during pregnancy. The study has been approved by the medical ethics committee of the AMC.

Purpose of the study

Birth defects are important causes of death during the neonatal period and long-term illness. Causes of severe birth defects are largely unknown. Through this study, our main aims are to better understand how a healthy unborn child develops, and on the other hand, which mechanisms are responsible for developmental problems such as birth defects. In the future, this knowledge may lead to better treatment of affected children.

In this study, we will focus on important developmental processes in all organs, including the placenta. After donation, we may perform an ultrasound, MRI or CT scan to visualise the anatomy. In some cases, we will also isolate specific organ cells (e.g. heart or liver cells) and maintain them under carefully controlled conditions in such a way that they can grow for weeks, or even months. These growing cells provide researchers with highly valuable information about organ function and development, which cannot be obtained by studying non-growing cells.

Location of the study

Storage of tissue and ultrasound, MRI or CT scans will be at the Amsterdam UMC, location AMC, in a specialised central biobank. All material and information is stored completely anonymously and cannot be traced back to you.

Although the donated material is stored centrally, research into the development or diseases of a specific organ are mainly performed by doctors and researchers who are specialised in that area, such as a (paediatric) cardiologist or (paediatric) neurologist. If a researcher from another Dutch university or from abroad asks us for permission to study material stored at our facility, we will allow this if possible; our aim is to facilitate increasing knowledge of normal and abnormal development and ensure that all tissues are optimally used to increase our understanding. Researchers can apply for this without payment. The material collected in this study can only be used for non-commercial purposes; commercial companies and institutions cannot apply for use of the material.

Duration of the study

All tissues will be stored for maximum duration of 50 years. By storing the material for such a long time, we ensure that all tissue can be optimally used and as many as possible important questions about development and developmental diseases affecting specific organs can be answered.

Voluntary cooperation

Participation in this study is completely voluntary. If choose not to participate, you do not have to provide an explanation. Your decision will have no consequences for the medical care or help to you and your partner.

If you consent to participate in this study, you can retract your permission until donation to the biobank is completed, without providing a reason. After the donation is completed, it will not be possible to retract your permission. All material is stored completely anonymously. Therefore, we will be unable to identify which tissue was donated by you after completion of the donation procedure.

Privacy protection

All tissues are stored anonymously, ensuring protection of your personal privacy. If you agree to participate, we you to complete and sign a permission form. This form will be stored separately in the (secured) biobank archive. This form will contain personal information. However, it will not be possible to trace the permission form and donated tissue back to one another.

Of course we will carefully follow all rules that apply to the use and storage of human tissue. These rules and regulations can be found in a separate document ("Fetal Aneuploidy Biobank"). If you would like to read these rules and regulations, you can obtain a copy of this document by contacting the lead researcher dr. de Bakker (b.s.debakker@amc.uva.nl or 06 50063079). All studies involving human material or participants are supervised. Supervision may be done by representatives of the AMC (the commissioner of this study) and representatives of the inspection of health care in the Netherlands (Inspectie Gezondheidszorg en Jeugd).

Additional questions

If you have any further questions after reading this information and discussing your options with your doctor, you can always contact the lead researcher dr. de Bakker. If you prefer to speak to a doctor who is not involved in the study, but who is familiar with all steps and procedures of the study, you can contact dr. Saskia Maas, clinical geneticist (s.m.maas@amc.uva.nl of 020 5668844).

We wish you strength in this difficult and emotional time.

With kind regards,

Dr. Bernadette S. de Bakker
Clinical embryologist

Appendix I
Information on donating fetal remains for scientific research

Permission form

Statement granting permission to donate fetal remains for scientific research

I have been informed sufficiently about the study. I have received written information and have been offered opportunities to ask questions about the study. My questions have been answered sufficiently. I had sufficient time to consider whether or not I wish to participate. I know that I can withdraw my permission, without needing to offer any explanation. I know that the time to withdraw my permission is limited as the tissues are stored anonymously and the origin can then no longer be determined when the donation is completed.

I voluntarily agree to participate in this study.

Name:

Place:

Signature:

Date and time*:

If applicable:

Name partner:

Place:

Signature:

Please fill in below in the case of a termination of pregnancy

Date and time* of the decision to terminate the pregnancy:

Date and time* when information about the study was provided:

* The date and time of the decision to terminate the pregnancy, of obtaining information on the study, and agreeing to participate in the study are needed to clearly document that the decision to terminate the pregnancy was made before information about the study was provided, and before permission to participate was asked.

Appendix II
Information on donating fetal remains for scientific research

Form to withdraw permission

Herewith I withdraw my permission to use fetal tissues for scientific research, given on (date), and I request the tissues to be destroyed.

I understand that the tissues can only be identified until the moment of storage of the tissue in the biobank, and no longer thereafter. Fetal tissue that has been stored anonymously can no longer be destroyed.

Name:

Signature:

Date: