FPM-E-007-EN v1.0 17.03.2021

Informed Consent to participate in drug or medical device trial when pregnant

[Title of the study and possible short name/code]

I have been asked to participate in the above-mentioned drug/device trial whose aim is to [briefly summarise the purpose of the trial]. In this trial, the state of my health will be monitored for the whole pregnancy / during pregnancy weeks XX-XX until the birth of the child and for XX days / weeks after the birth. I have been informed that if I wish for my child to participate in this trial after the birth, the legal guardian of the child must sign a separate consent about the participation of my child. A new information bulletin will be attached to the new consent.

I have received verbal information regarding this trial, and I have also received a written study information leaflet. I have read and understood the information received on the objective and implementation of the trial, the benefits and risks of the trial and my rights. I have been able to ask questions which have been answered, and I have had enough time to consider my participation. I have been pressured to participate in this trial. Information about the trial was given by [name of the nurse/physician].

I understand that my participation in this trial is voluntary and I know that I have the right to refuse my participation. I can withdraw my consent and discontinue my participation in this trial at any time before the end of the trial and without giving a reason. I am also aware that the data collected up to the termination of the trial or withdrawal of consent may be used as part of the research data and safety evaluation of the drug/device. The termination of the trial or the withdrawal of the consent does not in any way affect the normal treatment or monitoring of my pregnancy or the treatment during the birth.

I have received sufficient information about the collection, processing, storage and disclosure of my personal data in connection with this trial. I am aware that my information is processed confidentially and is not disclosed to third parties, and the sponsor of the trial will store my research data for at least [xx] years, after which the data is appropriately destroyed. I am aware that travel expenses and/or loss of earnings caused by participation in the trial will be compensated /will not be compensated.

I consent to the collection of the gene sample that is a part of the trial and analysis of the samples for genetic studies described in the information leaflet. I also consent to the storage of the samples until the end of the genetic studies, but not exceeding [xx] years, before they are destroyed. I may request that my samples are destroyed earlier, during year [xx].

To be filled in when necessary:

☐ I have discussed the participation with the other parent of the child that I am expecting and the positive view of the parent has been taken into account (if not present at the time of consent*).

With my signature I consent to participate in this trial voluntarily.

_____ _____

Signature of the person invited to participate in the trial *Date of birth or social security number*

_____ _____

Name in block letters *Date*

_____

The home address of the person invited to participate in the trial

☐ As the other parent, I have received information about this trial.

_____

The signature of the other parent (if present)*

_____ _____

Name in block letters *Date*

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Confirmation by the person obtaining the consent

- I have informed the person invited to participate in the trial about the trial and given that person a written information leaflet.
- The person invited to participate in the trial has had the chance to ask questions and receive answers.
- The person invited to participate in the trial has had sufficient time to consider and decide on their participation in this study.
- The person invited to participate in the trial has been told what happens to the biological samples collected during the trial.

_____ _____

Signature of study doctor/study nurse *Place and date*

_____

Name in block letters

This consent form is prepared in two copies, one for the subject and the other is archived in a study file.