Consent form

Evaluation of NIPT for analysis of chromosomal abnormalities in maternal blood in the first and second trimesters − the SMART study

Research subject's consent, participation in research study:

I have been given verbal information about the study and I have read the written information. I am aware that my participation in this study is voluntary and that I can, at any time and without stating any reasons, stop participating. This will not affect the care I am given. I have been given the opportunity to ask questions about the study and these questions have been answered. All source data collected until the date of withdrawal from participation in the study, will be retained in accordance with the law.

I have been informed about, and I consent to, the study staff accessing my medical records. I have also been informed about the data that will be made available for analysis, that blood samples will be sent to the USA for analysis and that information concerning me will be processed abroad, both in and outside the EU and the EES regions. I have been informed that the data collected in connection with the part of the NIPT test that will be reported back to me will not be decoded. This means that my name and personal ID (Social Security) number will be sent, together with the samples, to the USA for analysis. I understand that this is to enable the research staff to report the results to me in the securest possible manner. I understand that all other data made available for analysis will be coded and will not be traceable to my person.

I have been informed that DNA from the blood samples will be analyzed and that the results of the NIPT analysis of the blood samples will be reported to me but that these results do not constitute a diagnosis. I understand that I can, at any time and without stating any reasons, request that these samples be destroyed. I also understand that the samples will be handled in accordance with the Swedish Biobanks in Medical Care Act.

I understand the information I have been given and I hereby consent to participate in the study.

Research subject's signature: _____

Research subject's name: _____

Date: _____

Affirmation, study researcher:

I hereby affirm that I have given comprehensive information about the ongoing study to the above research subject. I have gone through and explained the purpose of the study to the research subject and she has been given the opportunity to ask questions and obtain answers.

Study researcher's signature: _____

Study researcher's name: _____

Date: _____

Consent form

Evaluation of NIPT for analysis of chromosomal abnormalities in maternal blood in the first and second trimesters − the SMART study

Parental consent, participation in research study:

I/we have been given verbal information about the study and I/we have read the written information. I/we am/are aware that participation in the study is voluntary and that I/we can, at any time and without stating any reasons, stop participating. This will not affect the care my/our baby is given. I/we have had the opportunity to ask questions and these questions have been answered. All source data collected until the date of withdrawal from participation in the study, will be retained in accordance with the law.

I/we have been informed about, and consent to, the study staff accessing my/our baby's medical records. I/we have also been informed about the data that will be made available for analysis, that blood samples will be sent to the USA for analysis and that information concerning my/our baby will be processed abroad, both in and outside the EU and the EES regions. No information will be traceable to my/our baby.

I/we have been informed that DNA from the blood samples will be analyzed and I/we am/are aware that any abnormal results of the analysis will be reported to me/us within a year. I/we understand that I/we can, at any time and without stating any reasons, request that these samples be destroyed. I/we also understand that the samples will be handled in accordance with the Swedish Biobanks in Medical Care Act.

I/we understand the information I/we have been given and I/we hereby consent to my/our baby participating in the study.

_____	_____
Parent's signature	Parent's signature
_____	_____
Parent's name	Parent's name
_____	_____
Date	Date

Affirmation, study researcher:

I hereby affirm that I have given comprehensive information about the ongoing study to the above parent(s). I have gone through and explained the purpose of the study to the parent(s) and she/they has/have been given the opportunity to ask questions and obtain answers.

Study researcher's signature: _____

Study researcher's name: _____

Date: _____

Version 2