Consent form: Prenatal screening with NIPT (TRIDENT-2 study)

- I have read the general leaflet "*Information about the screening for Down, Edwards' and Patau's syndrome*", and I know that specific information about the TRIDENT-2 study can be found on www.meeroverNIPT.nl. I know that if I choose to have screening I will have to make a choice between the combined test and the non-invasive prenatal test (NIPT). I have had the opportunity to ask questions, and all my questions have been answered to my satisfaction.
- Subsequently, I have chosen to have the NIPT. I know this test is only offered as a scientific study: the TRIDENT-2 study. I know that I have to pay for part of the test myself.
- I have been informed, to my satisfaction, about the TRIDENT-2 study. I know that participation in the TRIDENT-2 study is voluntary. I have had enough time to consider taking part in the study. I know that I can withdraw from the study at any time, and without mentioning any reason.
- I know that if I choose to have the NIPT, I have to make a choice of whether or not to receive "additional findings" from the test. I can tell my health care provider/midwife what I prefer. I know that my choice for this cannot be changed, once my blood is sent to the laboratory. If I want to be informed about the "additional findings", I am aware that this information can be given to me by someone other than my own health care provider. Moreover, I may be asked by a researcher to participate in research on the consequences of "additional findings".
- I know that my data will be kept for 15 years after the end of the study, and that it will be destroyed after that period.
- I know that during the screening, my personal data and test results will be stored in the medical record held by my health care provider. I know that the data will be kept in a protected national database (Peridos) and stored in a protected laboratory information system. I understand that the researchers can receive coded information from Peridos about my pregnancy (in other words, without my name or other personally identifiable information)
- I know that if I choose to have NIPT, the researchers can contact me through my health care provider/midwife, to provide additional information about my pregnancy or the outcome of my pregnancy.
- I know that if I choose NIPT, the researchers can ask my health care provider/midwife for medical information about the outcome of the pregnancy, and I agree to provide this information for use in the TRIDENT-2 study.
- **I grant** ☐

  refuse ☐ permission for **residual material** (for example my blood) and collected medical information to be **saved and used** for 15 years after the study, for additional scientific research into the improvement of NIPT and future research on pregnancy outcomes.

I agree to participate in the TRIDENT-2 study:

Name of participant: …… Date of birth: ___ / ___ / ____

Signature: …… Date: ___ / ___ / ____

Signature of health care provider/counsellor

I confirm that I have fully informed the participant about the study. If new information becomes available during the study period that may affect the participants' willingness to consent to participate, I will inform the participant in a timely manner.

Name of health care provider/counsellor: ……

Signature: …… Date: ___ / ___ / ____

The participant will receive a copy of this form. A signed form will be kept in the research file of the health care provider/counsellor for 15 years.