Consent form TRIDENT-2 study: Prenatal screening with NIPT

- 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 have had the opportunity to ask questions, and all my questions have been answered to my satisfaction.
- I know that the non-invasive prenatal test (NIPT) 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 specifying a 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 the test result can be given to me by someone other than my own health care provider. I am willing to be directly approached by a researcher to participate in research on the consequences of "additional findings".
- I agree to my data being stored for 20 years after the end of the study, and being destroyed after that period.
- I know that 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 stored in a protected national database (Peridos) and in a protected national laboratory information system. I agree to the researchers being able to receive information from these systems about my test result and any follow-up data.
- I agree to the researchers being able to contact me directly and via 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 request medical information from my health care provider(s), and that the information concerning the course and outcome of my pregnancy may be used for the study, including any follow-up data, for example, into the consequence of "additional findings" and in case NIPT fails, and I agree to this information being used for 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 20 years after the study, for additional scientific research on performance and 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 20 years.