GENETIC INFORMED CONSENT

☐ **PRENATAL DIAGNOSIS**

Please complete and sign the consultation certificate and consent form below.
The elements to be completed in this document must be provided. Failure to do so will prevent the prescribed genetic test(s) from being carried out.

Consultation certificate from the prescribing physician or the genetic counselor

(insert for prescribers)

I, the undersigned, Dr/Pr [*First name, Last name*] ……,
or Mrs/Mr [*First name, Last name*] ……, genetic counsellor*

Certify that I have received for consultation today:
Mrs/Mr [*First name, Last name*]……, Born on [*Date of birth*]……

Certifiy that I have provided him/her (or the person with parental authority or his/her guardian) with all the information mentioned in articles R. 1131-4 and R. 1131-20-1 et seq. of the French Public Health Code, as well as under the terms of the texts adopted for their application:

1. The characteristics of the disease under investigation, the means of detecting it, the degree of reliability of the tests and the possibilities of preventive measures, including genetic counselling, and care
2. The modes of genetic transmission of the disease under investigation, when known, and their potential consequences for other family members
3. That the examination may incidentally reveal genetic characteristics unrelated to its initial indication but knowledge of which would enable the person or members of his or her family to benefit from preventive measures, including genetic counselling, or care
4. That, if the diagnosis of this anomaly is confirmed, she is obliged to inform, by any means possible, the members of her family who may be concerned.

**In accordance with articles R. 1132-5 et seq. of the French Public Health Code*

Information and Consent of a Person's Genetic tests

(patient insert)

I, the undersigned, Mrs/Mr [*First name, Last name*] ……**, certify that I have received from the above-mentioned doctor, during today's medical consultation:**

1. Information regarding:
   - the risk of the unborn child having a particularly serious condition;
   - the characteristics of this condition;
   - the methods of diagnosis;
   - potential fetal medicine, treatment, or postnatal care options;

2. Information about the biological tests proposed to establish a prenatal diagnosis in utero, which I wish to undergo:
   - these test(s) require a sample of amniotic fluid, chorionic villi (placenta), fetal blood, or another fetal sample;
   - the procedures, risks, constraints, and potential consequences of each sampling technique were explained to me;
   - I was informed that a second sample might be necessary in case of technical failure, in which case I will need to sign a new written consent;
   - other conditions not initially targeted may be revealed by the test, potentially affecting pregnancy management and possibly requiring further investigations, including genetic testing of each parent;
   - I was informed that the test results will be communicated and explained to me by the prescribing physician.

I consent to the sampling (necessary for the performance of the examination(s)) of [*check the appropriate box(es)*]:

- ☐ Amniotic fluid
- ☐ Chorionic villi
- ☐ Fetal blood
- ☐ Other fetal sample:……

I also consent to the examination(s) for which this sample is taken [*check the appropriate box(es)*]:

- ☐ Cytogenetic tests, including molecular tests applied to cytogenetics;
- ☐ Molecular genetic tests;
- ☐ Fetal biochemical tests for diagnostic purposes;
- ☐ Biological tests for the diagnosis of infectious diseases

I have been informed:

- Of the possible consequences of an abnormal result, including the risk of familial recurrence.
- Of my right to withdraw this examination request at any time, to not be informed of the results, or to request the destruction of stored samples.

The technique used may reveal genetic information unrelated to the pathology concerned, but which could have an impact on my/our health or that of related persons, on my/our care and/or treatment. **I wish to be informed of these results.**	☐ YES ☐ NO
I accept, if my results appear to be medically essential for my relatives, that they may be communicated and used in an anonymized way, in their interest, even after my death.	☐ YES ☐ NO

This (or these) examination(s) will be carried out in a medical biology laboratory authorized by the Agence Régionale de Santé to perform them. The original of this document is kept in my medical file. A copy of this document is given to me and to the practitioner who will carry out the examinations. The medical biology laboratory in which the practitioner who carried out the examination works keeps this document under the same conditions as the examination report. I have had the opportunity to ask any questions I may have had to the geneticist or genetic counsellor who prescribed this examination, and I have received full and adequate answers.

Done in …… **, on** ……

PATIENT ID (*Signature*)	LEGAL REPRESENTATIVE ID (Signature)	PRESCRIBER (*Signature*)
Last name, First name, Date of birth:	Signature of 2 parents required for TRIO analysis (index case + 2 parents) *Last name, First name, Date of birth:* *Last name, First name, Date of birth:* If the patient is minor or an adult under guardianship, relationship to the patient:	*Last name, First name*