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# Information and Consent form...

1 copy must be sent to Biomnis along with the sample / 1 copy must be kept in the patient's medical file

### PRENATAL

# ...for pregnant women

**Biomnis** 

for the collection of a sample and the performance of one or more tests for the purposes of prenatal diagnostics in utero (as per Article R. 2131-1 of the French Public Health Code)

# I, the undersigned, .....

confirm that the doctor (Surname, First Name):

as part of a medical consultation on (date):

#### 1. Has given me information about:

- the risk of the unborn child being born with a particularly serious condition;
- the characteristics of this condition;
- the means of diagnosing it;
- the possible opportunities offered by foetal medicine for the treatment or care of the child after birth;

#### 2. Has given me information on the laboratory tests that could establish a prenatal diagnosis in utero; these tests have been offered to me and I wish to receive them:

- this (these) test(s) require(s) a sample of amniotic fluid, chorionic villi (placenta), foetal blood, or other foetal sample;
- the methods, risks, constraints and possible consequences of each sampling technique needed to perform this (these) test(s) have been explained to me:
- I have been informed that a second sample may be needed in the event of technical failure; in this event, I will need
- to sign a new written consent form;
- I have been informed about possible conditions other than those initially investigated that could be revealed by the examination;
- I have been informed that the result of the test will be given to me and explained by the doctor who prescribed it to me.

### I give my consent for the sampling of (required for the conduct of the test(s)) (\*):

- amniotic fluid
- chorionic villi
- foetal blood
- other foetal sample (please specify)

### I also give my consent for the test or tests (\*) for which the sample is being collected:

- cytogenetic tests, including molecular tests applicable for cytogenetics
- molecular genetics tests
- foetal biochemistry tests for diagnostic purposes
- laboratory tests for the diagnosis of infectious diseases

This (or these) test(s) will be carried out in a medical laboratory that is duly authorized by the regional health agency to conduct them.

The original copy of this document will be stored in my medical records. A copy of this document will be given to me and to the person responsible

for conducting the tests. The medical laboratory in which the person responsible for conducting

the tests is employed shall keep this document under the same conditions as the report of the examination.

### (\*) Delete as applicable

Date:

# Signature of the clinician

# POSTNATAL

# ...prior to the carrying out of genetic examinations of an individual

(French Decree n° 2008-321 dated 4 April 2008 - French Decree dated 27 May 2013)

To be completed prior to the carrying out of genetic examinations of the person concerned or their identification by genetic fingerprinting for medical purposes.

#### **DECLARATION OF INDIVIDUAL MEDICAL CONSULTATION** Pursuant to articles R. 1131-4 and R. 1131-5 of the French Public Health Code

I, the undersigned, ..... a medical doctor, and pursuant to articles R.1131-4 and R.1131-5 of the French Public Health Code.

Hereby certify that the patient mentioned above was received for a consultation today where information on the characteristics of the disease to be screened, the methods used to detect it and details on the possibilities of prevention and treatment were provided.

Signed in (city): ..... on (date):

Signature en bas du document

## CONSENT TO PERFORM GENETIC EXAMINATIONS

# I, the undersigned, (name of the Father)

born on L\_\_\_\_\_, Currently residing at:

I, the undersigned, (name of the Mother)

born on L\_\_\_\_\_, Currently residing at:

Hereby declare that I had a consultation with Dr .....

where information on the genetic tests to be performed was provided. These tests will be performed with the aim to:

- □ confirm or otherwise the diagnosis of a genetic disease in relation to my symptoms,
- □ confirm or otherwise the pre-symptomatic diagnosis of a genetic disease.
- □ identify the healthy carrier status of an individual (heterozygote screen or chromosomal rearrangement),
- □ assess my genetic susceptibility of being afflicted with a genetic disease or undertaking a medical treatment.
- As such, I consent to sample(s) being collected from me.
- I have been informed that the above-mentioned doctor will provide the results of this genetic examination during an individual consultation. If the exam reveals any results other than those specified on the original request, the aforementioned Doctor will determine the appropriate steps to be taken during the individual consultation.
- > Should any of the sample remain unused following examination:
- □ I consent to this sample being used, if needs be, for scientific research purposes. In this case, all personal medical data will be protected by it being made totally anonymous. Consequently, I am conscious that the scientific studies performed will not provide me with any advantage or prejudice.

Signed in (city): ..... on (date):

Signature of the Mother

Signature of the Father

**Biomnis** 

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