

# INFORMED CONSENT TO CONDUCT GENETIC STUDIES

I have been informed by Mr. \_\_\_\_\_ about the study of genes \_\_\_\_\_.

I understand that I may be a carrier of or affected by a genetic disorder, the diagnosis of which can be confirmed by the analysis of DNA or RNA obtained from a biological sample.

I have also been informed and understand the following terms and limitations associated with the study:

- The proposed genetic study is considered the best diagnostic strategy currently available for my specific clinical case. However, new clinical or scientific evidence may emerge indicating the need for further testing.
- The result may generate situations of diagnostic uncertainty due to the presence of infrequent alterations in the structure of DNA or RNA.
- In complex genetic studies, genetic information may be obtained that is not directly related to the objective of the study requested.
- I may be asked to provide a new sample if it is necessary to repeat the test, carry out additional studies or if the quality of the biological sample is not optimal.
- I understand that the identification of a pathogenic mutation indicates the disease, while non-identification does not guarantee the absence of the pathology.
- In the case of indirect or linkage studies, the results shall be expressed in terms of likelihood and their reliability shall depend on the diagnostic certainty and family informativity of the markers used. Such informativity is different across patients and populations.
- The report of the results shall be sent to my doctor, duly interpreted according to the clinical indications of the study.
- Once the genetic study has been completed, a duly coded DNA aliquot, shall remain in custody at the laboratory, in accordance with current legislation.

By signing this form, I agree to voluntarily participate in this test on my behalf or as a legal guardian. My Physician or Genetic Counsellor has answered all of my questions in this regard. This informed consent may be revoked at any time by written notice sent to NIMGenetics.

I declare that the personal and medical information I have provided is true and reliable.

I understand and agree that the clinical team may contact me for additional clinical data. I consent to the clinical data obtained from the test being used by my physician and/or the NIMGenetics laboratory for auditing, quality studies, and research purposes, provided that such information is anonymous, unidentifiable, and that all my or my child's personal information shall be removed from any report or publication.

## Patient or Legal Guardian:

Name: \_\_\_\_\_

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

## Medical Practitioner:

Hospital / Clinic / Laboratory: \_\_\_\_\_

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

In accordance with Law 41/2002 Regulating Patient Autonomy and Law 15/1999 on Personal Data Protection, the petitioner shall have the consent of the patient to carry out the diagnostic tests requested and for the processing of their data. Thus, and as information to be provided to the patient, we must inform you that the data collected in this form will be incorporated into a confidential automated file, duly registered with the Spanish Data Protection Agency, in accordance with the terms established in Law 15/1999, the ownership of which corresponds to NIMGenetics, SL, with the purpose of the processing diagnostic study described in the form, the patient being able to exercise at any time the rights to access, rectification, cancellation or objection, recognised by the regulations cited relating to Personal Data Protection, to be sent to the following address: NIMGENETICS, S.L., Genómica y Medicina, C/ Faraday, 7 28049 Madrid.

NIMGenetics is an ANALYTICAL DIAGNOSTIC CENTRE WITH A GENETICS UNIT, authorised and qualified to issue clinical diagnoses by the Community of Madrid (Clinical Diagnostic Laboratory, Health Activity Licence under registration number CS10673).