

Standard Operation Procedure: Informed Consent Form for Genetic Testing

Version 1.3

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| By International Division

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- 1 Introduction** It is compulsory that Biomnis receives the Informed Consent Form properly filled out and signed by the patient before processing any **DNA assay**, the result of which will be used to:
 - confirm or invalidate the diagnosis of or predisposition to a genetic disease.
 - search for heterozygote status with a view to obtaining genetic counselling.
 - search for a genes location.
- 2 Informed Consent Form** This form (see document following this procedure), has to be properly filled and signed by each patient whom blood sample is collected and sent to BIOMNIS FOR DNA TESTING.
- 3 Information given to the patient** The DNA test information is to be given by the Clinical Pathologist prescribing the test, or by the Physician collecting the sample. All relevant issues regarding the involved pathology etiology, development, prognosis and potential treatment must have been raised by the Genetics consultant or the Physician and clearly understood by the patient.
- 4 Informed Consent Form Transfer** The Informed Consent Form must follow the specimen, and will be kept by BIOMNIS as will any other clinical information associated with the patient's file.
- 5 Result reporting** The result must be reported to the Physician only and must be delivered directly to the patient during a consultation.

Practitioner Signature

Informed Consent Form for Genetic Testing

We the undersigned,

Name

.....

Address

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Confirm that we had the opportunity to discuss and have been informed by the Pathologist (Genetics Consultant), or Physician, Doctor about molecular studies that will be performed on DNA extracted from my blood/tissue to:

- confirm or invalidate the diagnosis of or predisposition to a genetic disease.
- search for heterozygote status with a view to obtaining genetic counselling.
- search for a genes location.

We give our consent and confirm that we have received all the necessary information according to the law.

Date

Patient Signature