

Standard Operating Procedure: Informed Consent Form for Genetic Testing

1 Introduction It is compulsory that Claymon Biomnis receives the Informed Consent Form properly filled out and signed by the patient before processing any **PRENATAL STUDY**, the result of which will be used to:

- confirm or exclude the diagnosis of or a predisposition to a genetic disease.
- determine heterozygote status with a view to obtaining genetic counselling.
- examine gene locus .

2 Informed Consent Form This form (see document following this procedure), has to be fully completed and signed by each patient whose blood sample is collected and sent to Claymon BIOMNIS FOR PRENATAL STUDY.

3 Information given to the patient The prenatal study 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 The Informed Consent Form must accompany the specimen, and will be kept by Claymon 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

I the undersigned,

Name

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Address

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Confirm that I had the opportunity to discuss and have been informed by the Pathologist/Genetics Consultant / Doctor about the PRENATAL STUDY that will be performed on cells and/or DNA extracted from my amniotic fluid to:

- confirm or invalidate the diagnosis of or a predisposition to a genetic disease.
- determine heterozygote status with a view to obtaining genetic counselling.
- examine gene locus.

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

Date

Patient Signature