CONSENT TO NON-INVASIVE PRENATAL SCREENING (NIPS)

CONFIRMATION AND INFORMED CONSENT OF PATIENT[i]

By providing a ☒ yes response to paragraphs 1 to 8 below [ii]and by providing a ☒ yes response to paragraph 9 in respect of data processing and by signing this Consent Form, I the undersigned confirm and consent to Genseq performing Non-Invasive Prenatal Screening (NIPS) genetic testing and processing of genetic data in the terms set out below:

1 I have received from my health practitioner[iii] all appropriate information concerning NIPS testing and processing of genetic data, including indication(s), purpose and scope, risks, potential outcomes and implications of NIPS, and alternatives to NIPS testing.
2 I have read or have had read to me the NIPS Patient Information Leaflet and understand the information provided to me in the information leaflet including the limitations of NIPS using illumina® VeriSeq v2.
3 I have had an opportunity to ask questions of my health practitioner in respect of the NIPS genetic screening test and processing of genetic data.
4 I have received satisfactory answers to all my questions from my health practitioner.
5 I have read or have had read to me the Test Request Form and confirm that the information provided in the Test Request Form is correct and complete.
6 I consent to the NIPS screening testing proposed by my health practitioner to be carried out by Genseq on my blood sample as ordered by my health practitioner in the Test Request Form[iv].
7 I consent to Genseq issuing the report on my NIPS test results to my health practitioner(s) whose details are provided in the Test Request Form including those registered under the health practitioner's account with Genseq.
8 I consent to the disposal of my residual blood sample after NIPS testing has been performed by Genseq.

I agree to the statements and confirm my consent to paragraphs 1 – 8 above ☐ Yes ☐ No

EXPLICIT CONSENT TO DATA PROCESSING

9 I give my explicit consent to the processing by my health practitioner as controller (and Genseq on their behalf) of my personal data including health and genetic data for the purpose of the provision of genetic testing services as described here (and in the NIPS Patient Information Leaflet) to include use of patient clinical and family history, sample receipt, processing, testing, reporting to and correspondence with my health practitioner(s), retention, storage and disposal of samples, DNA and the processing of related patient payment and billing information. In particular, I understand any residual sample[v] of maternal and foetal Deoxyribonucleic acid (DNA) will be retained for such period as may be specified by my health practitioner as controller of my personal data or as required by law prior to disposal of any such retained DNA. I understand that I have a right to withdraw my consent at any time and that to do so I will contact my health practitioner.

☐ Yes ☐ No

PATIENT	HEALTH PRACTITIONER
_____	_____
Patient (Full name - BLOCK LETTERS)	**Health Practitioner (Full name - BLOCK LETTERS)**
X_____	X_____
Patient (Signature)	**Health Practitioner (Signature)**
Patient DOB (dd/mm/yyyy) _____	**Professional Registration Number:** _____
Date (dd/mm/yyyy) _____	**Date (dd/mm/yyyy)** _____

CONSENT TO NON-INVASIVE PRENATAL SCREENING (NIPS)

CONFIRMATION BY HEALTH PRACTITIONER

I the undersigned confirm:

1 I am the health practitioner under whose responsibility NIPS genetic testing has been requested in respect of the patient named in the Test Request Form and the above Informed Consent and I owe a professional duty of confidentiality to the patient.
☐ **Yes** ☐ **No**

2 I confirm that the at the time the blood sample was drawn from the patient her pregnancy was at least 10 weeks gestation based on the results of an early pregnancy dating ultrasound scan[vi].
☐ **Yes** ☐ **No**

3 I have provided the patient with all appropriate information concerning NIPS testing and processing of genetic data, including indication(s), purpose and scope, risks, potential outcomes and implications of NIPS, and alternatives to NIPS testing and have provided a copy of the NIPS Patient Information Leaflet and have discussed the limitations of NIPS using illumina® VeriSeq V2.
☐ **Yes** ☐ **No**

4 I have given the patient an opportunity to ask questions and confirm that I have answered all questions asked by the patient.
☐ **Yes** ☐ **No**

5 I confirm that the patient consented to the NIPS test results being issued to the health practitioners whose details are provided in the Test Request Form including those registered under the health practitioner's account with Genseq.
☐ **Yes** ☐ **No**

6 I confirm that the patient has voluntarily given informed consent to NIPS genetic testing and processing of genetic data.
☐ **Yes** ☐ **No**

HEALTH PRACTITIONER

Health Practitioner (Full name - BLOCK LETTERS) _____ **Professional Registration Number:** _____

X _____
Health Practitioner (Signature) **Profession:** _____

Date (dd/mm/yyyy) _____

[i] NIPS screening consent form is for persons who are aged 16 years and over and have capacity to consent to undergo genetic screening. If a patient is under 16 or lacks capacity to consent to undergo genetic screening do not use this form. The patient's health practitioner can contact Genseq to discuss the individual patient's circumstances and potential options.

[ii] Genseq will not be able to provide NIPS Genetic testing and processing of genetic data where the Confirmation and Informed Consent of the Patient and / or Confirmation by Health Practitioner is incomplete or where a negative answer has been given to any of the X boxes. The blood samples is only suitable for testing within 10 days of the blood draw and an incomplete Test Request Form and / or Confirmation and Informed Consent of the Patient and Confirmation by Health Practitioner may mean that a new blood sample will be required when submitting the completed Test Request Form and / or the Confirmation and Informed Consent of the Patient and Confirmation by Health Practitioner.

[iii] Under section 42 of the Disability Act 2005 (as amended) ("**the 2005 Act"**) the informed consent of an individual undergoing genetic testing must be obtained prior to genetic testing and the processing of genetic data in compliance with the 2005 Act and GDPR. Under Irish law a health practitioner is a registered medical practitioner, dentist, pharmacist, nurse, midwife, optometrist, optician, or a registrant of a profession designated under the Health and Social Care Professionals Act 2005 (as amended) which includes registered psychologists and psychotherapists. See www.coru.ie for the full list of designated professions. In the informed consent and confirmation by Health Practitioner references to health practitioner are to a registrant of one of the designated professions or to a person who is subject to an equivalent duty of confidentiality to the individual whose health or genetic data is to be processed.

[iv] The Test Request Form contains important information relevant to patient consent. The Test Request Form is completed by the patient's health practitioner and specifies the test(s) to be performed on the patient's blood sample and provides Genseq with relevant patient information including pregnancy information. Genseq relies on the adequacy and accuracy of the information provided by the health practitioner in the Test Request Form. Genseq performs the specific test(s) listed in the Test Request Form and issues a report on the test(s) to the patient's health practitioner(s) whose contact details are set out in the Test Request Form including those registered under the health practitioner's account. By signing the consent form and providing the data protection consent the patient consents to Genseq performing the test (s) specified in the Test Request Form and to Genseq issuing the report on the test(s) result(s) to the health practitioner(s) whose contact details are provided in the Test Request Form including those registered under the health practitioner's account. Genseq allows access to the test results via its online portal to the patient's health practitioners including those registered under the patient's health practitioner's account with Genseq.

[v] Due to the nature of NIPS testing It is unlikely that there will be any residual sample of DNA as it will be used up or destroyed in the testing process.

[vi] illumina® VeriSeq V2 assay requires maternal peripheral whole blood samples from pregnant women of at least 10 weeks gestation and Genseq requires that gestational age is established by the patient's health practitioner based on early dating ultrasound test result to confirm that the pregnancy is at least 10 weeks gestation at the time that the blood sample is drawn.

Last Updated 24 June 2024