

Manchester Haemoglobinopathy Diagnostics Service
Telephone 0161 276 4880

Patient/Parental Consent for Haemoglobinopathy Genetic Screening

Use this consent form for pre conceptual, ante natal or pre-natal diagnosis

Part 1 – to be completed by the patient or their representative in all cases

Please read this consent form carefully. It describes the benefits and possible problems of the haemoglobinopathy genetic investigation tests discussed with you. You have the right to change your mind at any time, including after you have signed this form, by contacting the person who has explained the tests to you. You should be given your own copy of this consent form to take away.

I have had the following explained to me (or to the person with responsibility for the patient)

Name of proposed test (include brief explanation if required):

The intended benefits:

- To help make a diagnosis of a haemoglobinopathy genetic disorder
- To discover if a patient carries a genetic change that explains their blood test results
- To enable relatives to benefit from genetic testing, where needed
- To clarify the implications of a previous test
- To confirm the identity of a haemoglobin variant
- Other.....

Possible risks:

- The test may reveal unexpected information (including non-maternity/paternity)
- Risk of mistaken diagnosis
- Other.....

Consent for testing and any restrictions imposed:

- I agree to the proposed test(s) above.
- I **would/ would not** like to be told the results of my test.
- I **give/do not give** permission for the results of my test(s) to be released to my GP/referrer.
- I understand that my results may enable family members to benefit from genetic testing. **I hereby give consent** for genetic information that may be relevant to other family members to be made available to their doctor. **If you do not give this consent tick here**
- I understand that the sample may be sent to another laboratory for additional testing, if required,
- I understand that my DNA will be stored and that, for quality control and/or developing and standardising new tests, it may be necessary to use part of the sample anonymously.
- If I am unable to receive the result(s), I would like the results to be given to:

Declaration of consent

Please sign below to indicate your consent.

Signed:..... Date:

Name (PRINT):

Relationship to patient

Witness consent, if required

A witness should sign below if the patient is unable to sign but has indicated his or her consent.

Signed:..... Date:

Name (PRINT):

Part 2 overleaf – MUST be completed by the Health care professional obtaining consent

Copies of this form are available from

<https://mft.nhs.uk/the-trust/other-departments/laboratory-medicine/haematology/haemoglobinopathy/>

Information for individuals who carry alpha or beta thalassaemia can be obtained from: <http://www.chime.ucl.ac.uk/APoGI/data/html/hb/carriers/menu.htm>

Patient/Parental Consent for Haemoglobinopathy Genetic Screening – Part 2

Part 2 MUST be completed by the Health care professional obtaining consent in order for testing to take place.

Nature of test required:

- Blood sample to be analysed for:
- CVS to be analysed for:
- Amniotic fluid to be analysed for:
- Foetal blood to be analysed for:
- Previous DNA sample to be analysed for:
- Other (give details)

Statement of health professional (to be completed by a health care professional with appropriate knowledge of proposed procedure):

I have explained the procedure to the patient / parent. In particular, I have discussed, as outlined on page 1:

The intended benefits

Possible risks

Informed consent has been given, with any restrictions indicated on page 1 of this form.

Where indicated and requested, the use of the results of these tests to enable pre-natal diagnosis have been discussed with the individual(s) concerned (see page 3 for additional consent information required).

- I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative tests (including no test) and any particular concerns of those involved.
- The following additional information has been provided.....
- I have provided the patient with a signed copy of this consent form

Signed:

Date:

Name (PRINT):

Job title:

CONTACT TELEPHONE NUMBER:

Statement of interpreter: (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe they can understand.

Signed.....

Date.....

Name (PRINT).....

For individuals wishing to undertake prenatal diagnosis, please complete Part 3 below

Copies of this form are available from

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Patient/Parental Consent for Haemoglobinopathy Genetic Screening Part 3- Additional Consent for Prenatal Diagnosis (PND)

To be completed by individuals who agree to have chorionic villus sampling/amniocentesis or foetal blood sampling.

I certify that I have been counselled in relation to:

- Chorionic villus sampling**
- Amniocentesis**
- Foetal blood sampling**

It has been explained to me and I understand that the prenatal diagnostic process involves the following:

- There is a small risk of the procedure causing miscarriage.
- The procedure may involve local anaesthesia.
- I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
- An additional chromosome test may be done to check for common abnormalities
- If I am aged 37 or above by the estimated time of delivery, a further chromosome test (karyotyping) may be done to check for abnormalities.
- If karyotyping is required this will reveal the sex of the foetus.
Do you wish to know the sex? **YES** **NO**
- I, and the father, will be requested to provide a small additional blood sample prior to the PND process taking place. This is to provide an independent check of our original genetic test results.
- In rare circumstances laboratory tests do not produce a result or the result is uncertain, in which case I may be offered another test.

Patient: I have read and understood the above:

Signature:..... Date:.....

Name (PRINT):

Healthcare Professional: I have explained the PND procedure to the individual.:

Signed: Date:

Name (PRINT): Job title:

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