Module 3: Consent

St George's University Hospitals NHS
NHS Foundation Trust

Module 3 will cover:

- Pre-test counselling
- NIPT for the private payer
- The SAFE test consent form
- Key considerations for the health professional
- Key considerations for the patient
- Mandatory information

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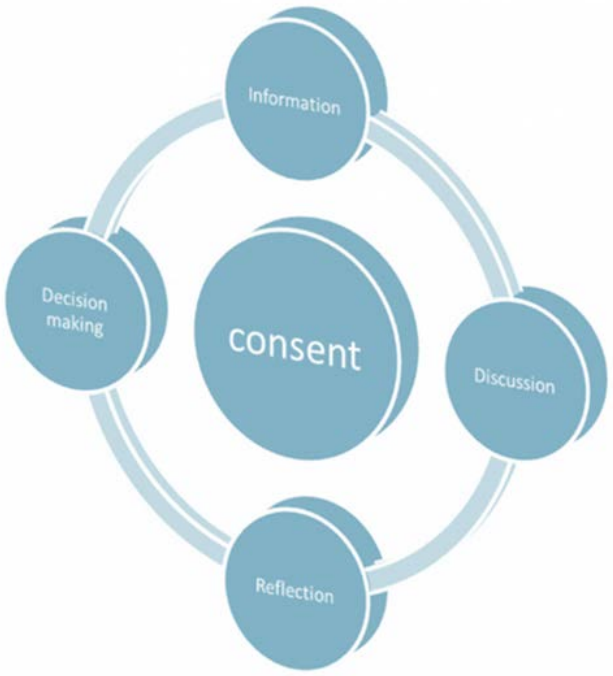
Introduction to screening consent

- The main aim when consenting an individual for any form of test is to provide:
  - Evidence-based balanced information
  - Options that are in line with a person's individual needs and preferences
  - A non-judgemental environment



- In accordance with NICE guidance, women and their families should have received appropriate information on screening and its consequences at first contact.

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Pre-test counselling: best practice

- Explain what cfDNA tests screen for
- What cfDNA tests do not screen for
- How the test is taken
- Performance (sensitivity) of the test
- How and when results will be given

Allow expectant parents the opportunity to ask any questions during and after the consultation

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Counselling women: Following a high chance trisomy result on combined or quad test

There should be further discussion on:

- Patient details: check patient/test result details concur
- Test: Ensure patient is aware of what test was performed and why
- Results: How the result was calculated and explain the chance/risk to patient
- Condition: What trisomy means and effect on the fetus
- Options: This should include discussion of NIPT, diagnostic tests or no further action
- Outcomes: Options and pathways available if the pregnancy is affected. Providing choice, consistent with an individual's culture, religion and beliefs

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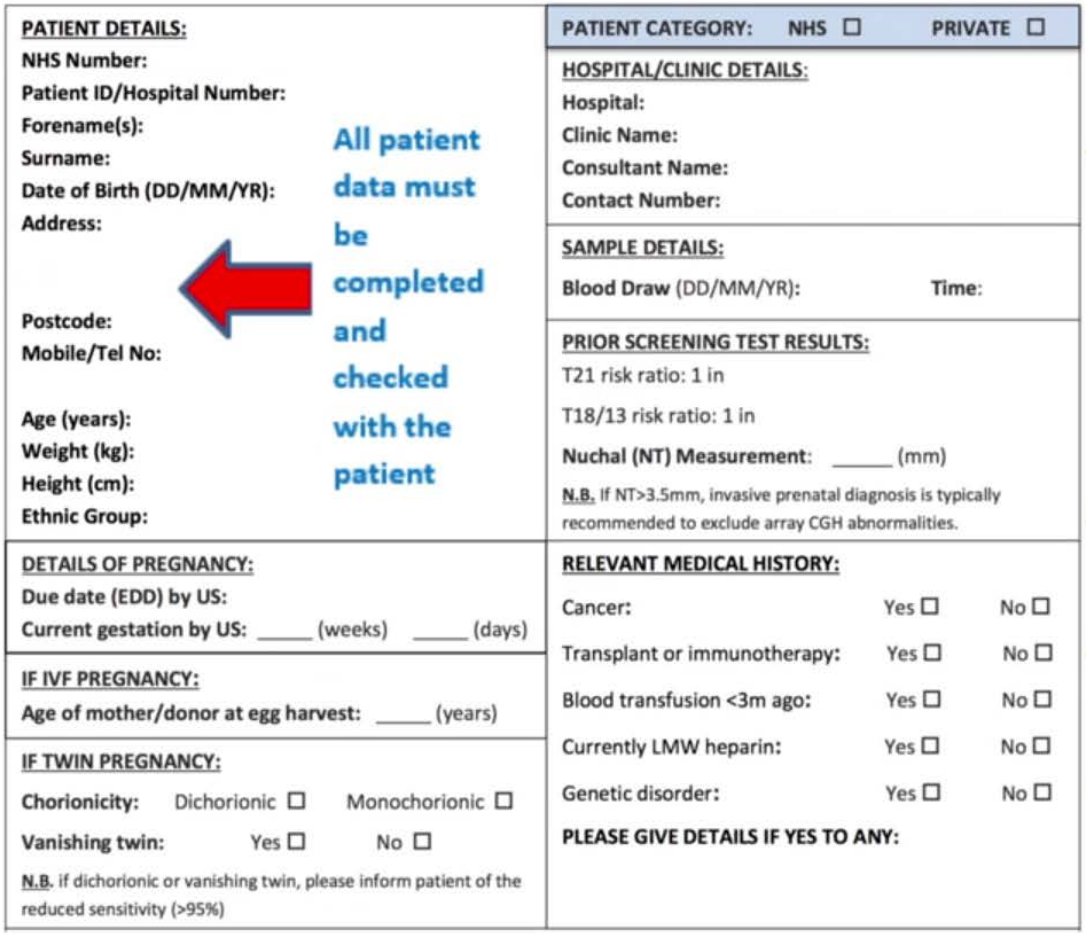
SAFE test consent form



PATIENT DETAILS:
NHS Number:
Patient ID/Hospital Number:
Forename(s):
Surname:
Date of Birth (DD/MM/YR):
Address:

Postcode:
Mobile/Tel No:

Age (years):
Weight (kg):
Height (cm):
Ethnic Group:

All patient data must be completed and checked with the patient

PATIENT CATEGORY: NHS ☐ PRIVATE ☐

HOSPITAL/CLINIC DETAILS:
Hospital:
Clinic Name:
Consultant Name:
Contact Number:

SAMPLE DETAILS:
Blood Draw (DD/MM/YR): Time:

PRIOR SCREENING TEST RESULTS:
T21 risk ratio: 1 in
T18/13 risk ratio: 1 in
Nuchal (NT) Measurement: _____ (mm)
N.B. If NT>3.5mm, invasive prenatal diagnosis is typically recommended to exclude array CGH abnormalities.

DETAILS OF PREGNANCY:
Due date (EDD) by US:
Current gestation by US: _____ (weeks) _____ (days)

IF IVF PREGNANCY:
Age of mother/donor at egg harvest: _____ (years)

IF TWIN PREGNANCY:
Chorionicity: Dichorionic ☐ Monochorionic ☐
Vanishing twin: Yes ☐ No ☐
N.B. if dichorionic or vanishing twin, please inform patient of the reduced sensitivity (>95%)

RELEVANT MEDICAL HISTORY:

Cancer:	Yes ☐	No ☐
Transplant or immunotherapy:	Yes ☐	No ☐
Blood transfusion <3m ago:	Yes ☐	No ☐
Currently LMW heparin:	Yes ☐	No ☐
Genetic disorder:	Yes ☐	No ☐

PLEASE GIVE DETAILS IF YES TO ANY:

Details not completed correctly may affect risk

Test may be inappropriate if NT >3.5mm

Incorporated into the test result

High-dose therapeutic heparin or other details may affect risk or cause test failure

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The consent form

PATIENT CONSENT:

My signature below indicates that I have:

- Read and understood the information provided.
- Been given the opportunity to ask questions.
- Received appropriate counselling about this type of screening from a healthcare provider.

I give my consent for my sample to be analysed using the SAFE test, or, through a carefully chosen contractor. I agree that the information provided may be used for auditing and quality control and that my data will be anonymised for such purposes. I understand that if I do not tick the relevant box below I give my permission for surplus sample and associated data to be stored and used as detailed on the reverse of this form.

☐ **Tick box to opt out of laboratory studies using surplus sample (plasma) and associated anonymised data.**

Patient Signature: Date:	Clinician Name (please print): Clinician Signature: Clinician Designation: Midwife ☐ Doctor ☐

The health professional and the patient are both required to print and sign

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Good clinical practice

- An ultrasound scan should always be performed prior to cfDNA testing to confirm viability, gestational age and confirm singleton or twin pregnancy
- Discuss all screening options, include all possibilities and limitations
- Signed, informed consent is essential
- Confirm that patient is aware that cfDNA testing is not a replacement for the routine first trimester ultrasound scan
- If increased NT or other anomalies are noted on ultrasound, further counselling and different testing may be required

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External resources

- ARC- Antenatal results and choices www.arc-uk.org
- DSA- Down's syndrome association www.downs-syndrome.org.uk
- SOFT UK- Support organisation for Trisomy 13/18- www.soft.org.uk
- NHS choices www.nhs.uk