

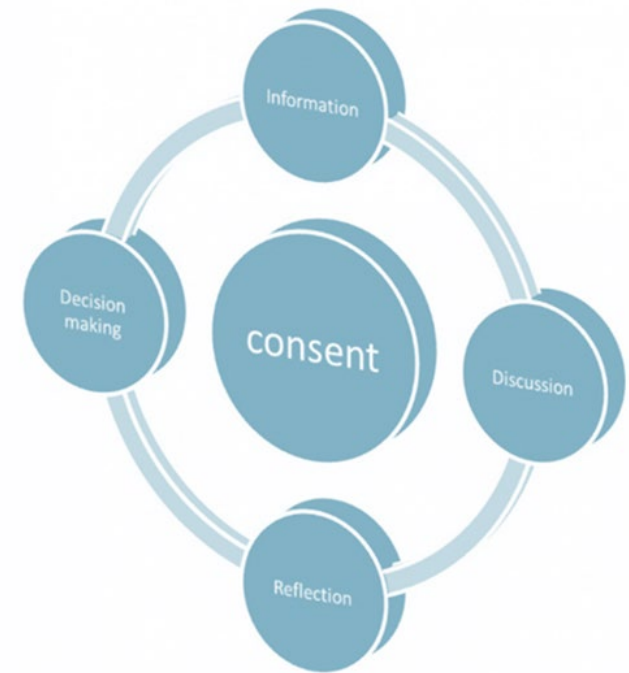
# Module 3: Consent

## Module 3 will cover:

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

# 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.



# 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.

# Counselling women: Following a high chance trisomy result on combined or quadruple 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:** Information on the condition that has been reported as high chance and contacts for relevant support organisations
- **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



# SAFE test consent form

- Patient Details – All patient data must be completed and checked with the patient
- Details of pregnancy – Gestation in weeks and days must be completed
- IVF pregnancy – age of the donor at egg harvest is required
- Twin pregnancies – Complete the chorionicity if known. Also note any vanishing twins
- Prior screening results will be incorporated into the test result
  - Test may be inappropriate if NT >3.5mm
- Relevant Medical History – may affect suitability for the test
  - Some conditions, treatments or procedures may affect risk or cause test failure
- Any details entered incorrectly may affect the risk calculation

# The consent form

<p><b><u>PATIENT CONSENT:</u></b></p> <p>My signature below indicates that I have:</p> <ul style="list-style-type: none"><li>• Read and understood the information provided.</li><li>• Been given the opportunity to ask questions.</li><li>• Received appropriate counselling about this type of screening from a healthcare provider.</li></ul> <p>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.</p> <p><input type="checkbox"/> <b>Tick box to opt out of laboratory studies using surplus sample (plasma) and associated anonymised data.</b></p>	
<p>Patient Signature:</p> <p>Date:</p>	<p>Clinician Name (please print):</p> <p>Clinician Signature:</p> <p>Clinician Designation: Midwife <input type="checkbox"/>      Doctor <input type="checkbox"/></p>

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

# 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.

# Further support available:

- ARC- Antenatal results and choices [www.arc-uk.org](http://www.arc-uk.org)
- DSA- Down's syndrome association [www.downs-syndrome.org.uk](http://www.downs-syndrome.org.uk)
- PADS – Positive about Down Syndrome <https://positiveaboutdownsyndrome.co.uk/>
- SOFT UK- Support organisation for Trisomy 13/18- [www.soft.org.uk](http://www.soft.org.uk)
- NHS [www.nhs.uk](http://www.nhs.uk)



**Down's Syndrome Association**

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