

The Consent Conversation:

- What is informed consent?
- What is distinct about Genetic testing in relation to informed consent?
- The paperwork and recording consent.



Informed Consent:

Valid consent is...



- voluntary
- informed
- with capacity to make a decision

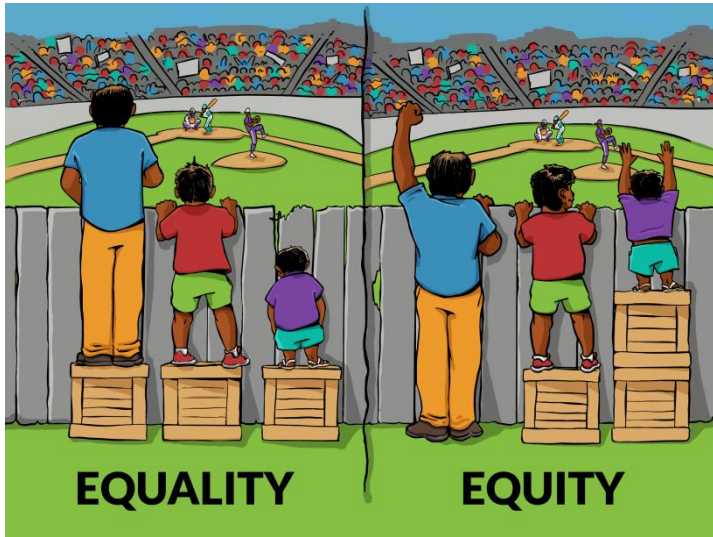
Is the patient sufficiently competent to make the decision?

- Assess this based on the Mental Capacity Act 2005 and/or Gillick test (for individuals <16 years).
- for patients who are non-English speaking, hearing impaired, visually impaired, or have learning disabilities, ensure that they have the resources or support available to allow them to participate fully in the consent discussion.



Has the patient been given the appropriate amount of information to help them make a decision?

- Assess individual information needs.
- What do they know already?
- Identify gaps
- Continually check understanding.



What the discussion could include.

- A description of the genes they are being tested for.
- A discussion of the implications for the patient.
- Implications for the wider family
- What the test will involve.

Was the consent given voluntarily?

- Pressure from other family members.
- **REMEMBER – just because you can test doesn't mean you should.**



What is distinct about genetic testing and informed consent?

- Implications for wider family.
- May reveal unexpected social relationships.
- Cant “cure” a genetic change.
- Can predict future health.
- Takes longer than some other tests.
- Results can be uncertain and complex.
- Information may change over time.

The Paperwork:

- Patient Information Leaflet



The Paperwork:

- Consent Form:

Cheshire & Merseyside Protocol for Genomic Testing of Patients with a Diagnosis of Breast Cancer

Consent

- I agree to have testing of my sample for genes involved in breast cancer.
- I understand that this test is not intended to diagnose whether I have or will get a cancer in the future. It is intended to tell me about my inherited genetic risk.
- I understand I will have the opportunity to discuss the test, its results and consequences in more detail.
- I understand my sample will be stored for possible future testing.
- I understand that my result and/or sample may be shared with health care professionals across the UK to help interpret genetic results and clarify the risks for others including other family members.

Signed (patient) _____

Name (PRINT) _____

Date _____

Signed (clinician) _____

Name (PRINT) _____

Date _____

Additional sources of information:

- **Insurance information:**

<https://www.abi.org.uk/data-and-resources/tools-and-resources/genetics/code-on-genetic-testing-and-insurance/>

- **Joint Committee on Genomics in Medicine (2019) provides a comprehensive overview of the specific issues of consent and confidentiality in genomic practice**

<https://www.rcplondon.ac.uk/projects/outputs/consent-and-confidentiality-genomic-medicine>