Sample Draft Retention of Tissue Patient Consent Form (Genetics)

- This is a Sample Draft Consent Form to help you draft your own Consent Form.

- This Consent Form is **suitable** for studies which involve genetic testing of blood samples or tissue samples.

- Section 4 of the Disability Act 2005 defines genetic testing as follows: "the examination of samples taken from a living person for the purpose of analysing the person's DNA or RNA by means of chromosomal analysis or by any other means for the purpose of (a) confirming the identity or nature of an existing symptomatic disease; (b) ascertaining whether the person has a genetic predisposition or susceptibility to a disease, or (c) identifying the carrier of a disease."

- Section 4 of the Disability Act 2005 defines genetic data as follows: "data relating to a living person derived from genetic testing of a person."

- This template has been created to assist healthcare professionals to design Patient Consent Forms for research studies taking place in Beaumont Hospital and involving patients.

- Not all bullet points and phrases in this template will apply to your particular study.

- If your study does not involve patients, watch out for words like 'patient,' 'future care,' 'medical care,' 'potential risks' 'medical records,' and 'storage and future use of information' as they may not apply.

- Instructions for using this template: Text in **Red** Font and **Blue** Font is for your guidance and instruction and should not appear in your final Consent Form.

Website: www.beaumont.ie

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Patient Consent Form (Genetics)

Note: Explain to the patient what the retention of samples for genetic purposes means or involves.

Study title:

I have read and understood the **Information Leaflet** about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	**Yes** ☐	**No** ☐
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future medical care.	**Yes** ☐	**No** ☐
I am aware of the potential risks of this research study.	**Yes** ☐	**No** ☐
I give permission for researchers to look at my medical records to get information. I have been assured that information about me will be kept private and confidential.	**Yes** ☐	**No** ☐
I have been given a copy of the Information Leaflet and this completed consent form for my records.	**Yes** ☐	**No** ☐
Storage and future use of information: I give my permission for information collected about me to be stored or electronically processed for the purpose of scientific research and to be used in related studies or other studies in the future but only if the research is approved by a Research Ethics Committee.	**Yes** ☐	**No** ☐

I agree to give a _____ [for example, blood, tissue, saliva, urine and so on. Delete as appropriate] sample or samples for this research project. I understand that giving a _____ [for example, blood, tissue, saliva, urine and so on. Delete as appropriate] sample or samples for this research is my own decision.	**Yes** ☐	**No** ☐
Storage and future use of biological material: I give permission for my samples and information collected about me to be stored for possible future research studies (including DNA or genetic studies) but only if the research is approved by a Research Ethics Committee.	**Yes** ☐	**No** ☐

Patient Name (Block Capitals)	Patient Signature	Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above patient the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

Name (Block Capitals)	Qualifications	Signature	Date

3 copies to be made: 1 for patient, 1 for PI and 1 for hospital records.

- **Remember to update the Footer in this document to include a Version Number and Date.**