**Sample Consent Form (updated 31 August 2018)**

* This is a Sample Consent Form to help you create your own Consent Form.
* This Consent Form is **not suitable** for studies involving the collection of blood or tissue samples.
* This template has been created to assist healthcare professionals to design Patient Consent Forms for research studies 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.
* All green text was inserted on the 25th May 2018, with a view to bringing this template in line with GDPR 2016, the Data Protection Act 2018, and the HSE Consent Policy 2017.
* All purple text was inserted, and certain words and phrases were underlined or **placed in bold font** on the 31st August 2018, as a result of feedback from principal investigators.
* This template was commissioned by the Royal College of Surgeons in Ireland and Beaumont Hospital and has been adapted for use by St. Francis Hospice, Dublin.

**PATIENT CONSENT FORM**

|  |
| --- |
| **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, benefits and alternatives 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** |
| I consent to take part in this research study having been fully informed of the risks, benefits and alternatives. | **Yes** | **No** |
| I give informed explicit consent to have my data processed as part of this research study. | **Yes** | **No** |
| I consent to be contacted by researchers as part of this research study. | **Yes** | **No** |

**Remove the table below if it does not apply to your study.**

|  |  |  |
| --- | --- | --- |
| **FUTURE CONTACT** **[please choose one or more as you see fit]** |  |  |
| **OPTION 1:** I consent to be re-contacted by researchers about possible future research **related** to the current study for which I may be eligible within the next 2 years of signing this form. | **Yes** | **No** |
| **OPTION 2:** I consent to be re-contacted by researchers about possible future research **unrelated** to the current study for which I may be eligible. | **Yes** | **No** |

**Remove the table below if it does not apply to your study – this table will only apply if you placed the paragraph entitled ‘Consent to Future Uses’ in your Patient Information Leaflet.**

**YOU MUST INCLUDE ALL OPTIONS**

|  |  |  |
| --- | --- | --- |
| **STORAGE AND FUTURE USE OF INFORMATION** | | |
| **RETENTION OF RESEARCH MATERIAL IN THE FUTURE [please choose one or more as you see fit]** | | |
| **OPTION 1:** I give permission for material/data to be stored for possible future research **related** to the current study **only if consent is obtained** at the time of the future research but only if the research is approved by a Research Ethics Committee within the next two years of signing this consent. | Yes | No |
| **OPTION 2:** I give permission for material/data to be stored for possible future research **related** to the current study **without further consent being required** but only if the research is approved by a Research Ethics Committee within the next two years of signing this consent. | Yes | No |
| **OPTION 3:** I give permission for material/data to be stored for possible future research **unrelated** to the current study **only if consent is obtained** at the time of the future research but only if the research is approved by a Research Ethics Committee within the next two years of signing this consent. | Yes | No |
| **OPTION 4:** I give permission for material/data to be stored for possible future research **unrelated** to the current study **without further consent** being required but only if the research is approved by a Research Ethics Committee within the next two years of signing this consent. | Yes | No |

| |

Patient Name (Block Capitals) | Patient Signature | Date

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Translator Name (Block Capitals) Translator Signature Date

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Guardian Name / Legal Representative Guardian Name / Legal Representative 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 Principal Investigator.

* **Remember to update the Footer on Page 1 to include a Version Number and Date.**
* **Remember to delete the Instructions at the start of this template.**