Patient Information Leaflet/Consent Form Template for Biomarker/Biobanking studies

Guidance for using this template document:

- **Use simple, clear language:**
  - Font size should not be less than size 12 in this document, and may need to be larger for some participant groups. Use a font that is easy on the eye, for example Arial or Calibri, not Times New Roman.
  - Make sure that people with no medical training or background can understand the words you use, see [www.simplyput.ie](http://www.simplyput.ie) for advice.
  - The National Adult Literacy Agency (NALA) can award a ‘Plain English Mark’ to your patient information leaflet, apply via [www.simplyput.ie](http://www.simplyput.ie)

- The PIL should ideally have a 2-page limit not including signatures page. Additional information can be provided in an appendix or faq sheet if necessary/requested.
- Not all the points below will apply to each study, Use only points relevant to your study
- All information leaflets and consent forms must be approved by the relevant research ethics commit prior to their use.

**Study Title:**

**Institution Name:**

**Principal Investigator Name:**

**What is the purpose of this research study?**

- Brief background on disease/condition being studied (1/2 sentences)
- Issue/clinical question being studied
- Why clinical samples needed
- If samples being collected for a biobank with no specific study, describe biobank and explain access policy for use of samples
- Aim of study

**Who is organising this study?**

- Study is being organised by X. e.g. research group belonging to an institution/commercial company
- Brief explanation/history of X
- Who is funding the study (if relevant)
Invitation to participate:

- Type of patients being invited to the study e.g. with X disease undergoing Y procedure
- Anticipated number of patients participating in study (if known) as well as number of centres/countries participating

Voluntary participation:

Participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. If you decide to participate in the study, you will be asked to sign and date this consent form. You will be given a copy of this signed and dated consent form. If you do decide to take part, you are free to withdraw from the study at any time and without giving a reason. This will not affect the standard of care you will receive. If you withdraw your consent, your samples that have already been collected will/will not be destroyed. Clinical information already gathered may/may not be continued to be used but no new information will be collected.

What will happen to me if I take part? (Study procedure)

- Duration of procedure
- What type(s) of sample will be collected, including how much (put volumes in mls and tablespoons)
- How and when sample will be taken including if sample(s) will taken at same time as routine appointment or requires an extra appointment.
- If sample (e.g. tissue) will undergo routine analysis in the hospital laboratory also
- What the sample(s) will be used for in study e.g. DNA, RNA, protein analysis
- What clinical information will be collected
- How long sample and clinical information will be stored for and where

What are the potential risks of taking part?

- If drawing blood: the procedure may cause local pain, bruising, infection, clotting of the vein at the site where the needle is inserted, and/or a fainting spell. Where possible, the research sample will be taken at the same time as routine bloods to minimise any discomfort.
- If any other risks e.g. tissue taken during surgery, list here.
What are the potential benefits of taking part?

- There are no direct benefits to you for participating in this study. Information obtained from the study may help in the understanding of the disease and in future diagnosis/treatment of the disease (if applicable).
- You will not benefit financially for participating in this study, nor from the results should they lead to the development of a new treatment/diagnostic.

What will happen to the results of the study?

- The information obtained from your sample(s) and clinical information will be combined with other patients to create the study results. The results of this study may be presented in study reports, at research meetings and/or published in medical journals. Any results obtained from your sample(s) and clinical information will not contain your identity.
- You will not be provided with your individual results.
- If results are to be made available publicly, explain where and when

Confidentiality

- All information which is collected about you during the course of the research will be kept strictly confidential.
- Describe how samples and data will be handled e.g. who will have access, who will know identity, if samples/information to be de-identified what is the process?
- State if medical records will be reviewed/information gathered and by whom
- State if GP/hospital doctor will be contacted as follow up
- State if file may be accessed for audit purposes by the hospital Research Ethics Committee/ relevant regulatory authorities e.g. Data Protection Agency, Irish Medicines Board or by company monitors and state that the auditors/monitors are bound by a strict code of confidentiality.
- State if information will be transferred to other locations e.g. company sites in other countries.

Ethical Approval

- State which hospital research ethics committee(s) has approved the study
Compensation for Injury

If you are harmed by taking part in this research project, there are compensation arrangements in place – outline insurance/indemnity arrangements in place if applicable.

If your study involves a risk and you have measures in place if the risk does materialise, let the participant know eg genetic counselling in case of certain genetic results, referral to a specialist is something is discovered etc:

Further Research

- State if further research may be conducted using the sample, using the e.g. DNA from the sample or using the clinical information
- State if further research may include genetic research
- State if further research will be restricted to the same disease/condition or not
- If there is an option not to authorise further research or to restrict further research to same disease/condition, include here
- State if they will be contacted in future to authorise further research

Who do I contact with questions?

- Give contact details: name, title, institution address, phone number and/or email of person who can be contacted
- If different people should be contacted in different circumstances, give all the details e.g. contact for general questions, contact for withdrawing from study, contact for medical emergencies/injury related to the study.
**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 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. 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). Yes ☐ No ☐

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(Patients should personally sign and date their own signature and be given a copy of information and signed consent form)

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.

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