**SITE LETTERHEAD**

**OPTIONAL patients aged 12-15 years INFORMATION SHEET AND INFORMED Assent FORM For Future SCIENTIFIC Research**

**(NAME OF STUDY)**

|  |  |  |  |
| --- | --- | --- | --- |
| Study title (lay): |  | | |
| Locality: | **XXX** | Ethics committee ref.: | **XXX** |
| Lead investigator: | **XXX** | Contact phone number: | **XXX** |

**Why have I been asked to give permission for a blood sample to be used in future scientific research?**

Because you are taking part in the study named above, you also have the option to supply a blood sample to be used for future scientific research if you want to. Please read through this information and ask your study doctor or nurse any questions if anything is unclear. You can then decide whether you want your blood sample to be kept for this purpose or not. If you decide that you will supply a blood sample to be used for future scientific research, please sign and date the Informed Consent Form (ICF) at the end of this Future Scientific Research Information Sheet to confirm you understand what it will be used for. You will receive a copy of this form.

**What is future scientific research?**

Scientists are making new discoveries all the time. It can take them years to find new techniques which can be helpful to improve medical situations for people in the future. They may discover new ways to test for the presence of (condition/disease), or ways of improving treatment for (condition/disease).

**Biomarkers**

Biomarkers are naturally occurring substances in your body which send messages to other parts of your body. Examples of biomarkers are proteins, and can be found in your blood or tissue. By testing if biomarkers are present and the amount of biomarkers present may help diagnose a certain disease, determine the severity of the disease, or evaluate how well and how effectively a medicine may treat the disease. Biomarkers may also determine if certain patients are more likely than others to benefit from treatment with a specific medicine. Some biomarkers for (condition/disease) have already been identified, but new discoveries are being made and new markers may be identified in the future.

**Genetic Testing**

You inherit genes from your parents. For example, genes give us the color of our eyes and hair, what we look like, if we develop certain diseases, and how we respond to some medicines. .  (the sponsor or researchers) may wish to test for genes that can cause (condition/disease) in order to help us make better medicines to stop or treat (condition/disease). (the sponsor or researcher) could perform the testing on the samples you have already given.

**What will (the sponsor or researcher) do with my blood sample?**

(the sponsor or researcher) will retain your blood sample to use when new discoveries become available for research related to (condition/disease). Your blood sample will be stored securely and confidentially.

(the sponsor or researcher), not the study doctor, will be conducting the future scientific or genetic research. For more information on future scientific or genetic research, please talk to your study doctor.

**Do I need to have additional tests or procedures?**

If you agree to allow future testing on your blood sample, you will not need to have an additional procedure to collect these samples. (the sponsor or researcher) will use the blood samples that were collected for the main study.

**How will my personal information be kept confidential?**

Your blood sample will be collected and protected. It will be helpful to the researchers to know some details about you, like your personal data, including sex, age, race, disease history, general health, and how you responded to this study medication. This information, along with other personal data, may be used by the researchers who are studying your blood sample, but they will not know your name. They will only have a number and partial date of birth. The results of this study may be published. Your name will not be used in any publications that result from the future scientific research.

**Can I still participate in the main study if I don’t give permission for (the sponsor or researcher) to use my blood sample** **for future scientific research?**

This is an option for you within this study. You can still take part in the main study, and it will not change any part of your medical care.

**Can I withdraw permission for my blood sample to be used for future scientific research?**

You can withdraw permission at any time. You must tell your study doctor. Any results from testing done before permission is withdrawn will remain the property of (the sponsor or researcher).

**Are there any benefits to allowing my blood sample to be used for future scientific research?**

It is unlikely that you will benefit directly from allowing a blood sample to be used for future scientific research. However, it may help people with (condition/disease) in the future.

You have the right to choose.

**Who do I contact for more information or if I have concerns?**

If you have any questions, concerns or complaints about the study at any stage, you can contact:

*Name, position*

*Telephone number*

*Email*

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(NAME OF STUDY)

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| --- | --- | --- | --- |
| Study title (lay): |  | | |
| Locality: | **XXX** | Ethics committee ref.: | **XXX** |
| Lead investigator: | **XXX** | Contact phone number: | **XXX** |

Participant's Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Full Name in BLOCK CAPITALS) (Month/Year)

* I have read this Information Sheet and Informed Assent Form or someone has read it to me. It is written in a language that I understand.
* I understand what I will be asked to do during this study, and I have had time to think about what the study involves for me.
* I have discussed it with the doctor/study staff, and they have answered my questions satisfactorily.
* I understand that it is up to me and I to decide whether or not to give permission for my blood sample to be used for future scientific research and that I can change my mind later.
* I understand that whatever I decide, my medical care and legal rights will not be affected.
* I understand that I will be able to keep a copy of this Information Sheet and Informed Assent Form for Future Scientific Research.

**❑ Yes, I agree** to allow (the sponsor or researcher) to use my blood sample for future scientific research.

**❑ No, I do not agree** to allow (the sponsor or researcher) to use my blood sample for future scientific research.

**❑ Yes, I agree** to allow (the sponsor or researcher) to use my blood sample for future genetic research.

**❑ No, I do not agree** to allow (the sponsor or researcher) to use my blood sample for future genetic research.

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| --- |
| **Participant’s Confirmation for Assent**    Name of Participant (Print)    Signature of Participant Date  **Statement of Person Obtaining Informed Assent**  I, the undersigned, have fully explained the details of this research study to the participant named above.    Name of Person Conducting Assent Discussion (Print)    Signature of Person Conducting Assent Discussion Date |