**SITE LETTERHEAD**

**OPTIONAL INFORMATION SHEET AND INFORMED Assent FORM For Future SCIENTIFIC Research (For patients aged 7 - 11 years)**

**(Name of Study)**

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

**Why has the study doctor asked if I can give my permission for a blood sample to be used for future research?**

As part of the study you are doing for the new experiemental drug you also have the option to give a blood sample to be used for future scientific research if you want to. Your study doctor or nurse will also tell you more about why it is being done. If anything is unclear, you can ask any questions you want to before you decide to do it or not. You can then decide whether you want your blood sample to be kept for this purpose or not. If you are happy to have a blood sample used for future scientific research, please sign and date the Informed Assent 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.

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

If you say YES to allow future testing on your blood sample, you will not need to have an additional needle to collect these samples. The blood that will be collected for the main study will be used for this purpose.

**What is future scientific research?**

Scientists work to make new discoveries to improve health for people. It can sometimes take them years to find new and better ways of doing things. They hope that your blood sample may help them discover new ways to test for (condition/disease), or ways of improving treatment for (condition/disease).

The scientists are thinking that in the future, they might be able to use your sample to help them make new discoveries in two areas:

1. ***Biomarkers -*** naturally occurring substances in your body which send messages to other parts of your body. These may also determine if some people with (condition/disease), are more likely than others to benefit from treatment with a specific medicine.
2. ***Genetic Testing –*** examples of genes are things we inherit from our parents, like 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/researcher) scientists are looking for any genes that might help them make better medicines, to stop or treat (condition/disease).

There is a tick box at the back of this form so you can choose if you want the scientists to use your blood sample for either, or both of these reasons. You won’t need to give another blood sample as they can perform the testing on the samples you have already given.

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

The sponsor will keep your blood sample to use when they discover something new related to haemophilia A. It could be kept for a long time. It is the company doing the research into the new study medication who will keep your blood sample, and not your study doctor.

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

YES. Your blood sample will be kept safe and protected by the researchers. They might find it helpful to know some things about you like how old you are, if you are a boy or a girl and if you have any other health problems, but they will not know your name or be able to identify you.

**Can I still do the main study and not give my blood sample** **for future scientific research?**

YES. You can still do the main study, and not give a blood sample for future research. You do not have to do this – you can choose.

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

YES. If you decide later that you have changed your mind and you now do not want your blood used for future research, just let your study doctor know. They won’t be able to un-do any research done before you change your mind though.

**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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**OPTIONAL INFORMED ASSENT FORM FOR FUTURE SCIENTIFIC RESEARCH**

**(For patients aged 7 - 11 years)**

|  |  |  |  |
| --- | --- | --- | --- |
| 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 they want me to give permission for my blood to be used for future research, and I have had time to think about it.
* I have discussed it with my mum, dad or legal guardian.
* The doctor/study staff has answered all my questions and I am happy with the answers.
* I understand that it is my choice 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 hospital care and rights will not change.
* 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) to use my blood sample for future scientific research.

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

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

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

|  |
| --- |
| **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 |