**University of Utah Model Informed Consent: Future Use of Biospecimens**

The following model language outlines the required components for future use of biospecimens at the University of Utah. The appropriate option should be selected based on the project. Modify as appropriate and as directed.

**Future Use of Biospecimens**

As part of this study, we would like to keep biospecimens and information about you so that researchers may use it in the future in other research projects. When we use the term “biospecimen bank”, it refers to the storage of the samples and information that is collected.

* **What will be kept?** We would like to keep a sample of your [insert specific biospecimen, e.g., blood, urine, tissue, etc.].
* **What will my sample and information be used for?**

*Option for specific disease/condition:* Your sample and information may be used in future research about [insert specific disease or condition] to help us learn more.

*Option for no specific disease/condition:* We don’t know what kind of future research will be done but we hope to learn more about diseases and how to treat them.

* **Who will keep my sample and information?**

*Option for University of Utah-managed biospecimen bank*: Your sample will be kept by Dr. [insert name] who manages the biospecimen bank at the University of Utah.

*Option for a sponsor-managed biospecimen bank:* Your sample will be kept by the study sponsor, [insert sponsor name], who manages the biospecimen bank.

* **Do I have to allow my sample and information to be saved for future research?**

*Option for mandatory biospecimen banking (e.g., sole purpose of research study is to save samples for future research):* If you do not want your samples and information to be saved for future research, you should not participate in this study. No matter what you decide to do, your decision will not affect your medical care.

*Option when choice given to bank biospecimens (note: participation in a biospecimen bank must be optional for treatment/intervention trials):* You do not have to participate in the biospecimen bank to be in the main part of this study. No matter what you decide to do, your decision will not affect your medical care. You can tell us your choice by initialing one of the choices below:

|  |  |
| --- | --- |
| **\_\_\_ YES,***(initial)* | my sample(s) may be saved for future [specify a specific condition/disease] research. |
| **\_\_\_ NO,***(initial)* | my sample(s) must be destroyed at the end of this research project. |

* **Will personally identifiable information be collected with my biospecimens?**

*Option for de-identified samples:* Your sample will not have your name or other personal information linked to it. No one will be able to tell that you gave us the sample. Your sample may be shared with researchers at the University of Utah and at other institutions without additional informed consent from you or your legally authorized representative. The only information we will keep with the sample is information like your age and what disease you have.

*Option for coded samples:* Your sample will be coded so that your name is not on the sample. Dr. [insert name] and the University of Utah will keep your name in a separate place so that we can link your sample back to you later if we need to. Your sample may be shared with researchers at the University of Utah and at other institutions without additional informed consent from you or your legally authorized representative. Dr. [insert name] will not give your name to other researchers who want to use your sample and will only give them information like your age and what disease you have.

*Option when choice offered regarding removal of identifiers:* We would like to code your sample so that your name is not on it. Dr. [insert name] and the University of Utah will keep your name in a separate place so that we can link your sample back to you later if we need to. But if you do not want us to keep your name or any other identifying information with the sample, you can choose to have your sample remain anonymous. You can tell us your choice by initialing one of the choices below:

|  |  |
| --- | --- |
| **\_\_\_ YES,***(initial)* | my personal identifiers can be kept with my sample(s). All information will be kept secure and confidential. |
| **\_\_\_ NO,***(initial)* | my name and identifiers must be removed from my sample(s). My sample(s) cannot be linked back to me. |

Your sample may be shared with researchers at the University of Utah and at other institutions without additional informed consent from you or your legally authorized representative.

* **What if I want to withdraw my samples from the biospecimen bank?**

*Option for de-identified samples:* Because we will not keep your name or other identifying information when we store your sample, you will not be able to have the sample removed from the bank later.

*Option for coded samples:* You can have your sample removed from this biospecimen bank later. You will need to contact [insert name] at [insert contact information].

*Option when choice offered regarding removal of identifiers:* You can have your sample removed from this biospecimen bank later. You will need to contact [insert name] at [insert contact information]. If you decide to have your identifiers removed from your sample, you will not be able to withdraw your sample later because it cannot be linked back to you.

* **Will my biospecimens be used for commercial profit?**  The use of your data and biospecimens may lead to new tests, drugs, devices, or other products or services with commercial value. These products or services could be patented and licensed. There are no plans to provide any payment to you should this occur.”
* **Will future results or findings be given to me?**

*Option for not disclosing future results:* Because the results from future research will not directly affect your health care, we will not share the results from future studies with you or your doctors.

*Option for not disclosing future results because of de-identification:* Because your sample cannot be linked back to you, we will not share the results from future studies with you or your doctors.