SAMPLE Consent Form for the Use of Specimens in Research

Your child is going to have [*Indicate procedure (e.g., surgery, biopsy, blood test)*] to [*treat or diagnose*] [*name of disorder*]. The doctor will remove (*type of sample*) to do some tests. (*Or, for example, “ normally the tissue that is removed is discarded”. Indicate if you are asking to remove additional specimen*). We would like to keep some of the (*type of specimen*)] that is left over for future research. If you agree, this (*type of sample*) will be kept and may be used in research to learn more about [*name of disorder or type of disorders*].

Reports about the research done with your (*specimen*) will not (*Note: if reports will be given to the physician, indicate so here by changing the wording.*) be given to you or your child’s doctor. These reports will not be put in your child’s health record. The research will not have an effect on your child’s care. Participation in this research is voluntary. Please read the information below and ask questions about anything that you do not understand before deciding whether or not to allow us to use the extra (*specimen*) for research.

# Purpose of Obtaining the Tissue

*⬩ State what the current study is designed to discover or establish.*

*⬩ State if the purpose is to store the specimen for future research.*

# Procedures

If you allow your child to be in this study, we will ask you to do the following things:

*⬩ If additional procedures will be done (e.g., blood test, buccal smear, etc) describe them in this section.*

*⬩ If you need to get information from the child’s health records, indicate it here.*

*⬩ If you will need to get permission to contact family members for more information, indicate it here.*

*⬩ If no additional procedures will be done, this section can be deleted.*

# Benefits

The research that may be done with your child’s (*specimen*) will not directly benefit your child. However, the information that we learn from the research might help other children who have [*name of the disorder*] and other diseases in the future.

# Potential Risks and Discomforts

The risk of allowing (*specimen*) for research is the unintentional release of information from your child’s health records. The *[names of facilities storing samples*] will protect your records so that the name, address and phone number will be kept private, unless you give permission to do otherwise. The risk that this information will be given to someone is small.

Sometimes health records have been used by insurance companies to deny a patient insurance or employers may not hire someone with a certain illness. *(if the next applies insert here)* The results of genetic research may apply not only to your child but also to your other family members. This is why Children’s will take careful steps to protect your research records.

*⬩ If there are other risks associated with the procedures indicated above, indicate those risks here.*

# Alternatives

You can choose not to have your tissue stored for research. Enough tissue needed for your care will still be kept. You can also choose not to allow use of your medical information.

# Possible Commercial Products

Children’s Healthcare of Atlanta (Children’s) or another institution designated by Children’s will own your child’s sample. If a commercial product is developed from this research project, it will be owned Children’s or an associated institution. You will not profit from the product.

Cells obtained from your child may be used to create a cell line which may be shared in the future with other researchers and which may be of commercial value. A cell line is a special set of cells that can grow for a long time in the laboratory. Cell lines can be useful because of the information we find out about certain diseases or because they may produce useful products.

Genetic research serves a number of purposes. These include medical knowledge, the development of new medications, tests and treatments and for public health tracking. Any medications, tests of treatments that may be developed might make money for Children’s or its research partners, but you will not share in any of these profits. You will not be paid for the use of your blood, tissue, or the information that they contain.

**Participation and Withdrawal**

Participation in this research is voluntary. If you choose not to allow use to use your child’s sample, it will not affect your relationship with Children’s or your right to medical treatment or other services and benefits to which you would otherwise be entitled to. If you decide to participate, you are free to withdraw your consent and stop participating at any time without affecting your relationship with Children’s. However, if you agree to have your sample shared with other researchers and later decide to withdraw, we may not be able to get back the entire sample.

**How to Obtain Information**

Daytime, Monday through Friday, 8:00 A.M. through 4:30 P.M. you may call Dr*. [Principal Investigator’s name*] at [*phone*].

**Rights of Research Subjects**

If you have questions regarding your child’s rights as a research subject, you may contact the \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(404) 785-\_\_\_\_\_\_.

**Privacy and Confidentiality**

Children’s will take precautions to make sure that information about you/your child is kept private. Your child’s name and other identifying information will be taken off anything associated with the (*specimen*) before it is provided to any other researcher, unless you give us permission to do otherwise. This will make it difficult for any research results to be linked to your child or your family.

**Results or New Findings**

The results of the studies of your samples may be made available to you or to your referring healthcare professional. It is your choice whether or not you want to know these results, and whether or not you want to have them reported to your health care provider for possible entry into your medical records.

# Choices for Uses of Your Child’s Information and Tissues

Please read the information below and indicate your choices for the use of your child’s information and tissue.

1. My child’s sample may be kept for use in research to learn about, prevent, or treat [name of disorder].

Yes No

1. My child’s sample may be kept for use in research to learn about, prevent or treat other health problems (for example x,y,z).

Yes No

1. My child’s sample may be shared with other researchers to learn about, prevent or treat [name of disorder] or other health problems that may be unrelated to my child’s illness.

Yes No

1. My child’s sample may be shared with other researchers to learn about, prevent or treat other health problems.

Yes No

1. Someone from Children’s may contact me in the future to take part in other research.

Yes No

1. The research on your tissue is not set up to give results that are useful to you or your doctor. However, if such results are found, do you want us to try to contact your referring doctor or primary care physician?

Yes No

1. (only if any of questions 1,2,3 were answered yes) My child’s samples may be identified in the following way (Initial all that you agree to):
2. With my child’s name and other identifying information. \_\_\_\_\_\_\_\_\_\_(initials)
3. With a code that is known only by Dr. [*Name*]. \_\_\_\_\_\_\_\_\_\_(initials)

1. My child’s sample may be released to researchers outside of Children’s Healthcare of Atlanta if there is no way to identify where it came from. \_\_\_\_\_\_\_\_\_\_(initials)

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| --- |
| **SIGNATURE OF RESEARCH SUBJECT OR LEGAL REPRESENTATIVE** |

Your signature(s) below indicate

* You have read this document and understand its meaning;
* You have had a chance to ask questions and have had these questions answered to your satisfaction;
* You consent to your child’s participation in this research study; and

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Subject

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name(s) of Parent(s)/Guardian

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent (Guardian) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent (Guardian) Date

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| --- |
| **SIGNATURE OF INVESTIGATOR** |

I have explained the research to the subject’s parent(s)/guardian and answered all of his/her questions. I believe that he/she understands the information described in this document and freely gives permission for his/her child to participate.

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Name of Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Investigator Date (must be the same date as subject’s)

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| --- |
| **SIGNATURE OF WITNESS *(If required by the Children’s IRB)*** |

My signature as witness certified that the parent(s)/guardian signed this permission form in my presence as his/her voluntary act and deed.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Witness

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness Date (must be the same date as subject’s)

Routing of signed copies of the consent form:

1. Give to parent or adult subject.
2. Place in the Children’s Medical Record

3) Place in the Principal Investigator's research file.

**Child’s Assent for Use of Specimens in Research**

**Children's Healthcare of Atlanta**

Why do you want to keep my extra tissue?

[*briefly outline the reason that is both appropriate to the child’s maturity and age*]. We are inviting you to be in the future study because [*state why the child is being asked to participate*].

What will happen to me?

[*Describe what will take place from the child’s point of view in language that is both appropriate to the child’s maturity and age*]

Will it hurt?

[*Describe any risks to the child that may result from participation in the tissue repository*]

Will the study help me?

[*Describe any benefits to the child from participation in the repository*]

What if I have any questions?

You can ask any questions that you have about the future study. If you have a question later that you didn’t think of now, you can call me [*insert study doctor’s telephone number*] or ask me next time. [*If applicable:* You may call me at any time to ask questions about your disease or treatment.]

Do my parents know about this?

This was explained to your parents and they said that you could be in it. You can talk this over with them before you decide.

Do I have to be involved in this?

You do not have to be involved in this. No one will be upset if you don’t want to do this. If you don’t want to be involved in this, you just have to tell them. You can say yes now and change your mind later. It’s up to you.

Writing your name on this page means that you agree to be in the study, and know what will happen to you. If you decide to quit the study all you have to do is tell the person in charge.

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Printed Name of Subject Age Date of Birth

Signature of Subject Date Time

Signature of Subject’s Parent/Legal Guardian Date Time

(Required for subjects under the age of 18 years)

Signature of Person Obtaining Assent/Consent/Permission Date Time

Signature of Witness Date Time