

## Parental Permission and Authorization Document

### BACKGROUND

We are asking your child to participate in our research study. Please take plenty of time to review the reasons we are doing the research and what participating would mean for your child. Please read the following information carefully and feel free to discuss it as needed. Ask us at any time if you have questions or do not understand something.

The purpose of this research study is to create syndrome-specific growth charts for Wolf-Hirschhorn Syndrome (4p-). We are doing this study because plotting growth points on an appropriate growth chart is a key piece of regular well-child care. The growth of children with Wolf-Hirschhorn is not the same as the growth of typical children. Therefore, the use of standard growth charts to follow children with Wolf-Hirschhorn provides inadequate information on their growth pattern, and may fail to alert their physician to a growth-related health problem. Furthermore, the failure of the child with Wolf-Hirschhorn to follow typical curves may be treated as a problem by his or her physician when, in actuality, his or her growth is appropriate in the context of the syndrome.

This study is being conducted by the University of Utah in concert with the 4p- Support Group.

### STUDY PROCEDURES

In order to create appropriate growth charts for children with Wolf-Hirschhorn, we need growth data from a large number of children with Wolf-Hirschhorn. If you decide to allow your child to participate in the study, we would request that you supply us with growth data on your child. This would include height, weight, head circumference, and the age at which these were obtained. We will be able to use this information in nearly any format you choose, including copies of the tables typically submitted with the 4p- Support Group bio forms, copies of medical records, or copies of standard growth charts. We will provide a table along with these consent documents that can be used to submit these data. The information can be submitted by fax, email, or standard mail.

Fax: (801) 585-7252 Attn: Dr. Amy Calhoun. This is a secure fax.

Email: [acalhoun@4p-supportgroup.org](mailto:acalhoun@4p-supportgroup.org)

Mail: Amy R.U.L. Calhoun, MD  
Department of Pediatrics, Division of Medical Genetics  
50 N Medical Drive  
SOM Rm 2C412  
Salt Lake City, UT 84132

### RISKS

The main risk of this study is that your child's growth data might be viewed by someone other than those of us to whom you gave permission to view it.

### BENEFITS

**FOOTER FOR IRB USE ONLY**  
Version: B0111

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We cannot promise that there will be any direct benefit to your child for participation in our study, especially if he or she has already completed his or her growth. However, as soon as we complete our study, we will be publishing the growth charts and making them widely available for use in all medical settings for children with Wolf-Hirschhorn/4p-.

### ALTERNATIVE PROCEDURES

You are absolutely free to decline to participate in this study. This will in no way affect your participation with the 4p- Support Group or your child's medical care.

### CONFIDENTIALITY

As soon as we receive your child's growth data, we will immediately remove all identifiers (for example, his or her name and birth date) and place his or her growth data into an anonymous spreadsheet, which will be kept on a secure, password-protected computer. We will keep all research records that identify your child private to the extent allowed by law. Unless legally required to do otherwise, Dr. Calhoun, Dr. Carey and Amanda Lortz are the only people that will have access to the original documents. Original documents will be stored in a locked cabinet in a locked office or in a secure folder on a computer that is password protected. We will destroy all of the original documents once the study is finished.

We may publish the eventual results of the study, but your child's data will be grouped with other children's and no one will be able to tell which pieces of data came from your child. No identifying information on any of the children will be included in any publication.

### PERSON TO CONTACT

If you have any questions or concerns complaints or if you feel you have been harmed by this research please contact Amy R.U.L. Calhoun, MD, Department of Pediatrics, Division of Medical Genetics at (801) 581-8943 or email at [acalhoun@4p-supportgroup.org](mailto:acalhoun@4p-supportgroup.org).

**Institutional Review Board:** Contact the Institutional Review Board (IRB) if you have questions regarding your child's rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu).

**Research Participant Advocate:** You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at [participant.advocate@hsc.utah.edu](mailto:participant.advocate@hsc.utah.edu).

### VOLUNTARY PARTICIPATION

If you decide to allow your child to take part you are still free to withdraw your child at any time and without giving a reason. Refusal to allow your child to participate or the decision to withdraw your child from this study will involve no penalty or loss of benefits to which your child is otherwise entitled. If your child doesn't take part, your child can still receive all standard care that is available to your child. This will not affect the relationship you or your child has with your child's doctor or other staff, nor decrease the standard of care that your child receives as a patient.

### COSTS AND COMPENSATION TO PARTICIPANTS

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The only foreseeable costs of participation in this study would include postage (if needed) and possibly copying or records fees from the participant's physician. There is no compensation for participation in this study.

**AUTHORIZATION FOR USE OF YOUR CHILD'S PROTECTED HEALTH INFORMATION:**

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your child's health for this research study. You can choose whether or not your child will participate in this research study. However, in order for your child to participate you have to sign this consent and authorization form.

This is the information we will use:

- Name (in order to prevent duplicate data being entered)
- Information from a physical examination, specifically: the date of the exam, age at exam, height, weight, and head circumference
- Standard pediatric growth charts
- Date of birth

Others who will have access to your child's information for this research project are the University's Institutional Review Board (the committee that oversees research studying people) and authorized members of the 4p- Support Group and Primary Children's Medical Center who need the information to perform their duties (for example: to ensure integrity of the research).

In conducting this study, we may share your child's information with groups outside the University of Utah Health Sciences Center and Primary Children's Medical Center. The information we share may include information that directly identifies your child. These are the groups:

- The 4p- Support Group

Information disclosed to groups outside the University of Utah Health Sciences Center and Primary Children's Medical Center may no longer be covered by the federal privacy protections.

You may revoke this authorization. **This must be done in writing.** You must either give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to

Amy R.U.L. Calhoun, MD  
Department of Pediatrics, Division of Medical Genetics  
50 N Medical Drive  
SOM Rm 2C412  
Salt Lake City, UT 84132

If you revoke this authorization, we will not be able to collect new information about your child, and your child will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

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This authorization lasts until this study is finished.

**CONSENT:**

I confirm that I have read this parental permission document and have had the opportunity to ask questions. I will be given a signed copy of the parental permission form to keep.

**I agree to allow my child to participate in this research study and authorize you to use and disclose health information about my child for this study, as you have explained in this document.**

\_\_\_\_\_  
Child's Name

\_\_\_\_\_  
1<sup>st</sup> Parent/Guardian's Name

\_\_\_\_\_  
1<sup>st</sup> Parent/Guardian's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to Child for 1<sup>st</sup> Parent/Guardian

\_\_\_\_\_  
Name of Person Obtaining Authorization and Consent

\_\_\_\_\_  
Signature of Person Obtaining Authorization and Consent

\_\_\_\_\_  
Date

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