Consent and Authorization Document

BACKGROUND

We are asking you 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 you. 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 people with Wolf-Hirschhorn. If you decide to participate in the study, we would request that you supply us with your growth data. 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
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 growth data might be viewed by someone other than those of us to whom you gave permission to view it.

BENEFITS

There will not likely be any direct benefit of your participation in the study. 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-.

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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 medical care.

CONFIDENTIALITY

As soon as we receive your growth data, we will immediately remove all identifiers (for example, your name and birth date) and place your growth data into an anonymous spreadsheet, which will be kept on a secure, password-protected computer. We will keep all research records that identify you 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 data will be grouped with other people's and no one will be able to tell which pieces of data came from you. No identifying information on any of the participants 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.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your 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.

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.

VOLUNTARY PARTICIPATION

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

COSTS AND COMPENSATION TO PARTICIPANTS

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.

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AUTHORIZATION FOR USE OF YOUR 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 health for this research study. You can choose whether or not you will participate in this research study. However, in order 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 information for this research project are the University's Institutional Review Board (the committee that oversees research studying people) and authorized members of the University of Utah Health Sciences Center, Primary Children's Medical Center, and the 4p- Support Group 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 you, and you 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. This authorization lasts until this study is finished.

CONSENT

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

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

_____
Participant's Name

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Authorization and Consent

_____ _____
Signature of Person Obtaining Authorization and Consent Date

If the participant is unable to give consent and authorization, consent and authorization is given by the authorized personal representative of the individual:

LEGALLY AUTHORIZED REPRESENTATIVE CONSENT STATEMENT:
I confirm that I have read this consent and authorization document. I have had the opportunity to ask questions and those questions have been answered to my satisfaction. I am willing and authorized to serve as a surrogate decision maker for

_____.
Participant's Name

I have been informed of my role and my obligation to protect the rights and welfare of the participant. I understand that my obligation as a surrogate decision maker is to try to determine what the participant would decide if the participant were able to make such decisions or, if the participant's wishes cannot be determined, what is in the participant's best interests. I will be given a signed copy of the consent and authorization form to keep.

_____
Name of Authorized Personal Representative

_____ _____
Signature of Authorized Personal Representative Date

Indicate the legal representative's authority to act for the individual:
☐ Spouse
☐ Adult (18 years of age or over) for his or her parent
☐ Individual with power of attorney
☐ Guardian appointed to make medical decisions for individuals who are incapacitated

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