

# Wilhelm Foundation

SANDBACKEN, 186 97 BROTTBY, SWEDEN – WILHELMFOUNDATION.ORG

## ***Informed Parental Consent for publishing picture(s) and medical summary of my child on the UDNI web page***

### **Informed Consent Form for \_\_\_\_\_**

This informed consent form is for parents of adolescent girls and boys with an undiagnosed disease participating in “Finding diagnoses through sharing”

### **Wilhelm foundation Finding diagnoses through sharing**

#### **This Informed Consent Form has two parts:**

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you agree that your child may participate)**

#### **You will be given a copy of the full Informed Consent Form**

### **Part I: Information Sheet**

#### **Introduction**

I am Mikk, and I work with Wilhelm Foundation in Stockholm. Wilhelm Foundation is collaborating with Italian Institute of Health (Istituto Superiore di Sanità, ISS) who is hosting the UDNI web site. UDNI is International Network for Undiagnosed Diseases.

I am trying to help girls and boys that suffer from an undiagnosed disease to get a diagnosis by showing their picture and story in the dedicated “patient area” section of the the UDNI web page ([www.udninternational.org](http://www.udninternational.org)). Whenever information is published about children, we talk to the parents and ask them for their permission. After you have heard more about the collaboration, and if you agree, then the next thing I will do is ask your daughter/son for their agreement as well. Both of you have to agree independently before I can begin.

You do not have to decide today whether or not you agree to have your child participate in this collaboration. Before you decide, you can talk to anyone you feel comfortable with.

There may be some words that you do not understand. Please ask me to explain them and I will. If you have questions later, you can ask them of me or of another people involved in the collaboration.

#### **Purpose**

The purpose of this collaboration is that doctors and researchers should be able to see a picture of children with undiagnosed disease and read about them. It is possible that someone will become interested and hopefully be able to help out so that the child can get a diagnoses. They might have seen children with similar symptoms.

**Type of Research Intervention**

A questionnaire has to be filled out and one or more pictures submitted

**Selection of Participants**

We want children with undiagnosed diseases to participate on the web page to increase the possibility to get a diagnoses.

**Voluntary Participation**

You do not have to agree to put your daughter/son's information on the UDNI web site. We know that the decision can be difficult when it involves your children. And it can be especially hard when the information and pictures of your child are exposed on the internet. You can ask as many questions as you like and we will take the time to answer them.

Participation is voluntary.

**Procedure**

1) You will get a questionnaire to fill out. It will require that you get information from your child's medical records or help from your child's doctor. If you don't wish to enter any information to some of the questions included in the questionnaire, you may skip them and move on to the next question. The questionnaires will be destroyed after they are transferred to the web page (see 3 below)

2) When the questionnaire is filled out we want you to email it to us together with some pictures of your child that you or your child's doctor thinks are good for other doctors to see.

3) We will pull the information from the questionnaire and enter that into a web page together with one or more of the pictures you sent us.

**Duration**

We are asking you to fill out the questionnaire which will take a fair amount of your time. Then finding existing pictures and/or take new ones of your child. You will also have to scan them if they aren't digital photos.

**Risks and Discomforts**

We are asking you to share your son/daughters de-identified but still personal information on the internet, you or your child may feel uncomfortable with this being public. It's impossible to guarantee that your child won't be recognized by the picture(s) and the information together. It's also possible that the pictures and/or the information is copied from the website.

**Benefits**

There might or might not be a benefit to your child, but your child's participation is making it more likely to find a diagnoses and we hope that a diagnoses will help your child and possibly others with the same condition.

## **Reimbursements**

You or your daughter/son will not be provided with any payment to take part in this collaboration

## **Confidentiality:**

We will not be sharing any information about your son or daughter outside of the UDNI Network. The information that we collect for this collaboration will be kept confidential. Information about your child will be de-identified. Any information about your child will have a number on it instead of his/her name. Only the Wilhelm foundation will know what his/her number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except yourself.

You should know, however, that we cannot stop or prevent visitors to the UDNI webpage from sharing the picture(s) and/or information.

## **Sharing of Research Findings**

If we receive interest or suggestions about your child we will immediately share this information with you.

## **Right to refuse or withdraw**

Participation is voluntary. Withdrawal is possible at any time and data will be erased in accordance with GDPR.

## **Who to Contact**

If you have any questions you may ask them now or later, even after the picture or information is published on the UDNI web site. Please contact any of the following:

Mikk Cederroth, Sandbacken 186 97 Brottbys Sweden, +46851241894, mikk@wilhelmfoundation.org  
Helene Cederroth, Sandbacken 186 97 Brottbys Sweden, +46851241894, helene@wilhelmfoundation.org

This proposal has been reviewed and approved by [name of the IRB], which is a committee whose task it is to make sure that participants are protected from harm. If you wish to find out more about the IRB, contact [name, address, telephone number.]

## ***Question to elucidate understanding:***

- *Do you know why we are asking your child to take part in this collaboration? Do you know what the collaboration is about?*
- *If you decide that your child's picture(s) and information should be published on the UDNI web site, do you know how much work you will have to put in to answer the questionnaire? Do you know that we will need one or more pictures in digital form? Do you know if you want you can stop participating at any time?*
- *Have you understood correctly the benefits that your child might have if you allow UDNI to publish picture(s) and information about him/her on the web site? Do you know that you won't be re-imbursed?*
- *Did you understand the procedures that we will be using to make sure that any information that we receive about your child will remain confidential? Do you understand that we cannot guarantee that the picture(s) and information about your child published to web site isn't shared in other places.*
- *Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the persons who can give you more information about the collaboration?*
- *Do you have any more questions?*

**PART II: Certificate of Consent**

**Certificate of Consent**

I have been asked to give consent for my daughter/son to participate in this collaboration which will involve hers/his picture(s) and medical information to be published on the UDNI web site (www.udninternational.org) - "Finding diagnoses through sharing".

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily for my child to participate as a participant in this collaboration.

**Print Name of Parent or Guardian** \_\_\_\_\_

**Signature of Parent of Guardian** \_\_\_\_\_

**Date** \_\_\_\_\_

**Day/month/year**

**Statement by the person taking consent**

I have to the best of my ability made sure that the person understands that the following will be done: The child's picture(s) and medical information will be published on the UDNI web site to hopefully find a diagnoses for the child who is undiagnosed.

I confirm that the parent was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the parent or guardian of the participant

**Print Name of person taking the consent** \_\_\_\_\_

**An Informed Assent Form will not be completed.**