

# Wilhelm Foundation

SANDBACKEN, 186 97 BROTTBY, SWEDEN – WILHELMFOUNDATION.ORG

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***Informed Assent Form***  
***for Children/Minors aged 6 up to 12 years old***  
***with undiagnosed rare disease***

An Informed Assent Form **does not replace** a consent form signed by parents or guardians. Child assent is in addition to the consent of parents and attests the child's willingness to participate to the study.

**Name of Patient Organization:** Wilhelm Foundation

**Name of the Network:** Undiagnosed Diseases Network International (UDNI)

**This Informed Assent Form has two parts:**

- **Information Sheet (gives you information about the study)**
- **Certificate of Assent (this is where you sign if you agree to participate)**

**You will receive a copy of the full Informed Assent Form**

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## Part I: Information Sheet

Hi, I am Mikk, and I work with Wilhelm Foundation in Stockholm. I am going to give you information and invite you to be part of a study carried on by doctors and scientists around the world.



We have discussed this study with your parent(s)/guardian and they know that we are asking for your agreement. If you wish to participate in the study, your parent(s)/guardian also have to agree. However, if you do not want to take part in it, you do not have to, even if your parents have agreed.

You may want to discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about.

Please ask me to stop at anytime and I will take time to explain.

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Doctors from all over the world want to help you and other children to treat your condition and make you feel better. The study we are proposing consists in creating a big website with information and pictures with children and adults with undiagnosed rare diseases around the world.

The website will help doctors that are visiting children with undiagnosed conditions like yours to find other children with similar conditions and this may help them understand what is your problem and what works better for you.

If you wish to participate, we should publish some of your pictures on the website. The pictures will be seen by many people, especially doctors and other people with undiagnosed rare conditions. They may be seen by other people as well.



We are asking you to help us solving some mysteries related to your condition and to find other children filling like you. If you have any fear or doubt about participation we can discuss this together. You don't have to feel obliged to participate.

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If you don't want to be in this study, you don't have to. Its up to you. If you decide not to be in the study, it is okay and nothing changes.

However, if you change your mind and decide to participate later on you can still contact us...

Similarly, if you decide to participate now, you can always change your mind later and it will still be okay, we will stop sharing your pictures and other information.

➤ **Question to elucidate understanding:**

*Do you know that you do not have to take part in this research study, if you do not wish to?  
Do you have any questions?*

**I have checked with the child \_\_\_\_ (initial) and he/she understands that participation is voluntary.**

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## PART 2: Certificate of Assent

*I understand the study is about sharing some pictures and information of myself and that some doctors and scientists all over the world could see the pictures, and this may help them to make me and other children feel better. I understand that other people may see the pictures as well.*

**I have read this information (or had the information read to me) and I had the possibility to make questions. I had my questions answered and I know that I can ask questions later if I want.**

**I agree to take part in the study.**

*OR*

**I do not wish to take part in the study and I have not signed the assent below. \_\_\_\_\_ (initialled by child/minor)**

### Only if child assents:

**Print name of child** \_\_\_\_\_

**Signature of child:** \_\_\_\_\_

**Date:** \_\_\_\_\_  
**day/month/year**

### *If illiterate:*

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the study team). Participants who are illiterate should include their thumb print as well.

**I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

**Print name of witness (not a parent) \_\_\_\_\_ AND Thumb print of participant**

**Signature of witness** \_\_\_\_\_

**Date** \_\_\_\_\_  
**Day/month/year**



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**I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.**

**Print name of the person who administer** \_\_\_\_\_

**Signature of the person who administer** \_\_\_\_\_

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

**Day/month/year**

**Statement by the person taking consent**

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:**

- 1.
- 2.
- 3.

**I confirm that the child 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 assent form has been provided to the participant.**

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

**Signature of person taking the assent** \_\_\_\_\_

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

**Day/month/year**

**Copy provided to the participant** \_\_\_\_\_ **(initialed by researcher/assistant)**

**Parent/Guardian has signed an informed consent** \_\_\_Yes \_\_\_No \_\_\_(initialed by researcher/assistant)