



# The SCOUT-O15 Study

A RESEARCH STUDY FOR CHILDREN AND  
ADULTS WITH PRADER-WILLI SYNDROME

Informed Assent Flipchart





# INTRODUCTION

**Welcome to the  
SCOUT-O15 Study!**

The SCOUT-O15 Study is a clinical study in children, adolescents, and adults with Prader-Willi Syndrome (PWS).

Before deciding whether or not to take part in the SCOUT-O15 Study, it is important to understand:

Why the study is being done	What it will involve
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- You are being invited to take part in the SCOUT-O15 Study because you have Prader-Willi Syndrome (PWS).
- Before deciding whether or not to take part, it is important to understand why the study is being done and what it will involve.
- We are going to review some key points to help you better understand the study.
- It is your choice if you want to join the study, so please ask any questions you may have.

## DISCUSSION QUESTION

Before we continue, do you have any questions about PWS or about why you have been invited to take part in this study?



# Welcome to the SCOUT-015 Study!

The SCOUT-015 Study is a clinical study in children, adolescents, and adults with Prader-Willi Syndrome (PWS).

Before deciding whether or not to take part in the SCOUT-015 Study, it is important to understand:

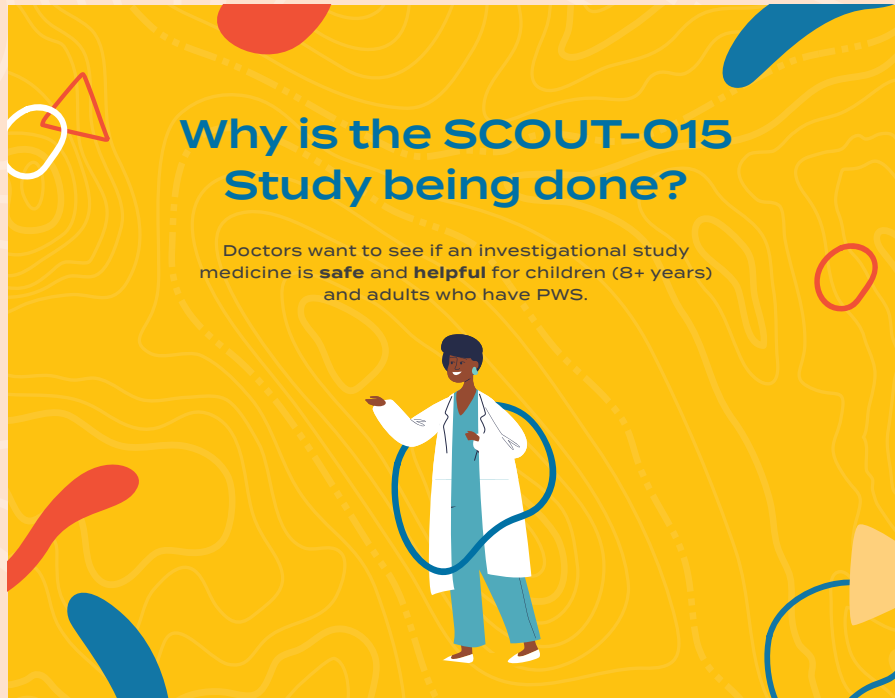
**Why the study is  
being done**

**What it will  
involve**





# STUDY OVERVIEW



- Doctors do research studies to learn more about what a specific treatment does in people with a specific health condition.
- In this study, doctors want to see if an investigational study drug is safe and helpful for children aged 8 years and older and adults who have PWS.



# Why is the SCOUT-015 Study being done?

Doctors want to see if an investigational study medicine is **safe** and **helpful** for children (8+ years) and adults who have PWS.





# STUDY DURATION AND VISITS



- The study lasts about 40 weeks, which is about 10 months.
- There are 3 parts: screening, study treatment, and follow-up.
- You will see the study doctor at the study clinic 10 times and talk by phone or video call 6 times.
  - Visits will be less frequent as the study progresses.



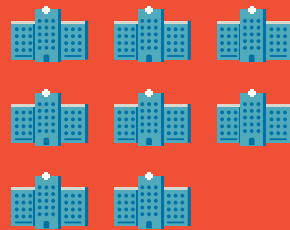
# How long is the study?

About 40 weeks

Screening



Study  
Treatment



Follow-up





# SCREENING



## DISCUSSION QUESTION

Some of these tests might not be familiar to you. Which tests would you like to know more about?



- First, you and your parents/guardian will need to read and sign forms. The forms tell you about the study. Signing them means you agree to be part of the study.
- Then, the doctor will do health checks and tests to see if the study is right for you, such as:
  - Asking questions about your health and the medicines you take.
  - Measuring your height and weight.
  - A checkup of your body.
  - Asking you or your parents/guardian to fill out forms with questions about how you feel, your symptoms of PWS, and about everyday life.
  - Blood tests.
  - Urine tests, which means you have to pee in a cup.
  - A pregnancy test, if you are able to get pregnant.
  - A heart test called an electrocardiogram, or ECG, to check your heart.
  - A DEXA scan (*if available at the clinic*), which is a painless, open-air, full body scan to check your bone, muscle, and fat.
- Note, you may not have all of these tests.

# What happens during screening?



Sign informed  
assent



Medicine  
review



Health  
information



Vital  
signs



Weight and  
height



Physical  
exam



Questionnaires



Heart test  
(ECG)



Blood  
tests



Urine  
test



Pregnancy test  
(if applicable)



Side effects  
review



# STUDY TREATMENT



- The study medicine is a liquid that you drink with food, twice a day about 12 hours apart.
- The liquid could have the active study drug in it or placebo. Placebo looks and tastes the same as the active study drug but has no real medicine in it.
- Having some people take the active study drug and some take the placebo helps doctors understand which effects are happening because of the active study drug and not by chance.



# What is the study treatment?



A liquid that you drink with food, twice a day about 12 hours apart.



# STUDY TREATMENT VISITS



- When you come to the study clinic, you will have health checks and tests like the ones that were done at screening.
- Sometimes, someone from the study team will call you and your parents/guardians at home by phone or video call.
- The study doctor will also check for any unwanted effects, called side effects, from the study treatment or study tests.

## Food diary

- You or your parent/guardian will be asked to fill out a food diary 4 times during the study.

## DISCUSSION QUESTION

Can you explain why it would be important for you to come in for clinic visits and tests and complete the food diary?



# What happens at study treatment visits?



Medicine review



Health information



Vital signs



Weight and height



Physical exam



Questionnaires



Heart test (ECG)



Blood tests



Urine test



Pregnancy test (if applicable)



DEXA scan (if available at your study clinic)



Side effects review



**Food diary**

4 times during the whole study. The same person will need to complete the food diaries throughout the study.



# DOSE DECREASE AND FOLLOW-UP

**What happens at the end of the study?**

You will stop taking medicine and have final health checks and tests.

- Medicine review
- Health information
- Physical exam (only at study clinic)
- Side effects review

- At the end of this study, you will stop taking the study medicine.
- You will have a final clinic visit and a final phone or video call to check on you.



# What happens at the end of the study?

You will stop taking medicine and have final health checks and tests.



Medicine review



Health information



Physical exam  
*(only at study clinic)*



Side effects review





## What are good and bad things about being in a research study?

<ul style="list-style-type: none"><li>• Study treatment may help</li><li>• Regular checkups</li><li>• Talk to doctors with experience with patients like you</li><li>• May help other people with PWS in the future</li></ul>	<ul style="list-style-type: none"><li>• Study treatment may not help</li><li>• Side effects</li><li>• Giving up time for study visits</li></ul>
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### DISCUSSION QUESTION

Can you tell me what you understand about some good and bad things about taking part in the study?



There are risks and benefits to any research study.

### Possible Benefits/Advantages

- The study treatment may help with your PWS.
- You'll have regular checkups and can talk to doctors with experience with patients like you.
- Information learned from the study may help other people with PWS in the future.

### Possible Risks/Disadvantages

- The study treatment may not help.
- There could be side effects from the study drug or study tests.
- You have to give up some of your time to come for study visits.

### Remember:

- Being in the study is your choice and you can decide to leave the study at any time.
- We may ask you to come for one final follow-up visit if you do decide to leave early.

# What are good and bad things about being in a research study?

- Study treatment may help
- Regular checkups
- Talk to doctors with experience with patients like you
- May help other people with PWS in the future

- Study treatment may not help
- Side effects
- Giving up time for study visits





# EXPECTATIONS

**What is expected of me during the study?**

- Come to all study visits
- Follow directions
- Take the study medicine as you are told to
- Be open and honest with the study team

**What happens next**

1. Take time to decide if you want to join
2. Talk with your family
3. Ask questions

- Come to the study visits and do your best to follow directions.
- Take the study medicine as you are told to.
- Be open and honest with the study team.

## **What Happens Next?**

- Take time to decide if you would like to take part in the SCOUT-O15 Study.
- Talk it over with your family.
- Ask the study doctor any questions you may have.
- If you decide to join, you will give your permission by signing the Informed Assent Form.



# What is expected of me during the study?

- Come to all study visits
- Follow directions
- Take the study medicine as you are told to
- Be open and honest with the study team

## What happens next

1. Take time to decide if you want to join
2. Talk with your family
3. Ask questions



# The SCOUT-O15 Study