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**IMPORTANT: CLINIC STAFF MUST SCAN A COPY OF THE SIGNED CONSENT FORM IN THE PATIENT'S CLINIC FILE. KEEP THE ORIGINAL SIGNED COPY FOR THE SToP STAFF (PUT IN THE SToP TRIAL FILE).**

**PLEASE ORDER ON IMPREST "SToP IVERMECTIN" (NOT NORMAL IVERMECTIN).**

The **SToP** Trial: **See Treat Prevent** skin sores and scabies  
A healthy skin programme in communities in the Kimberley

## Information sheet for adults, children, and parents/carers

*Ivermectin to treat scabies*

**Please ask your health worker questions at any time**

### Who is doing this project?

Researchers from **Telethon Kids Institute** in partnership with **Kimberley Aboriginal Medical Services (KAMS)** and **WA Country Health Service, Kimberley Region (WACHS – Kimberley)**. The lead investigator is Dr Asha Bowen from Telethon Kids Institute.



### What is this project about?

**Scabies** is a skin infection that makes you itchy. It is caused by a tiny mite that gets under the skin.

Scabies might make you very sick if you don't take medicine. We want to give you medicine to get rid of the scabies and prevent scabies from making you sick.

Usually the first medicine we give someone for scabies is cream medicine (lyclear). The cream medicine is oily and you have to put it all over your body. Sometimes it might come off.



**We want to know if a pill medicine for treatment of scabies (instead of the Lyclear cream) might help get rid of scabies in your family and your community.**

We think this pill medicine might work better because it may be easier to use.




The pill medicine is called Stromectol (ivermectin).



### What we would like to do

We want to work together with Aboriginal communities, parents, kids, schools, and health workers to help stop skin sores and scabies. We are asking you or your family to take part in the SToP study because of contact with scabies (including living and/or sleeping in the same house with someone who has scabies).

**This means we are asking you if you and/or your child want to:**

Action	Why?
 <p>Before we give you and/or your child the scabies pill medicine, we talk to you and/or your child to make sure you understand the scabies pill medicine. If you want to take part, we ask you to sign a consent form.</p>	<p>We want to make sure you understand the scabies pill medicine and why we are asking you and/or your child to take it.</p>
<p><b><i>If it's okay for you to take the pill medicine and you say yes, we will:</i></b></p>	
 <p>Give you and/or your child the scabies pill medicine (Stromectol/ ivermectin) to take. You take it 2 times over 1 week - today and 1 week later.</p>	<p>We think the scabies pill medicine will work better and is easier to take. There is no need to apply the cream onto your skin. If the SToP study works, we hope less people get scabies.</p>
<p><b><i>We would also like to:</i></b></p>	
 <p>Look at you and/or your child's clinic records for up to 7 days after your child took the scabies pill medicine.</p>	<p>We want to make sure the scabies pill medicine worked and you and/or your child felt OK after taking the medicine.</p>

### What if I say no?

It's okay to say no. It's your choice. You and/or your child will still be given the Lyclear cream medicine for scabies. If you want to take part, you can also change your mind at any time and stop – just tell us.

### Are there any benefits to being in the study?

The benefit is that you and/or your child will receive a different kind of medicine (the pills) than what is normally given (the Lyclear cream) and that this is easier to take to get rid of scabies. We will also ask people you are in close contact with (living and/or sleeping in the

same house) if they want to take the pill medicine. This will help stop them from getting scabies and help stop scabies coming back again.

### Are there any risks from being in the study and is the medicine safe?

The scabies pill medicine is safe for most people to take. The clinic staff will talk to you about whether it's safe for you and/or your child to take. It's not safe for some people, including:

- Females who are pregnant
- People who weigh less than 15kg
- People who are taking some other medications
- People whose liver is sick
- Some older people

If it is safe for you to take, sometimes, but not often, it can cause rash or diarrhoea or vomiting. If you have the scabies pill medicine and get sick or your family are worried, please go to the clinic to get checked out and tell them why you are worried.

### Who will have access to my information?

Only the clinic staff and study team working can see you and your child's names and information. Your names and personal information will be kept private. This means we won't show it to anyone outside of the study team.

### What happens to the information collected about me?



We only collect information that is needed to do the study. You and your family won't be identified in any way when we share results. All information will be locked up on a computer. The results of this study may be published in scientific journals or presented at scientific or community meetings but we will not use you or your family's names.

If you give permission to do the SToP study, the study staff will look at you/your child's clinic records and collect information about your health and the scabies pill medicine. Any information they collect will be stored on a secure computer but names will not be kept next to that information. No one will be able to match your name to the health information.

All electronic information will be kept on the Telethon Kids Institute server and a secure, password-protected online database that can only be accessed by authorised team members. Any paper documents will be stored in a locked cupboard/room that can only be accessed by authorised team members. Information will be kept for a minimum of 25 years, after which it will be destroyed as per Telethon Kids Institute's Information Retention & Disposal Policy and with authorisation from the lead investigator. Electronic records are digitally destroyed prior to disposal. Paper records are destroyed by shredding.

### Will you tell us about the results of the study?

Yes, we will tell you. We will tell everyone about the results. We will talk with communities and participants to tell them about the results and we will provide you with written information about the results too.

### Has this project been approved?

All research in Australia involving humans is checked by a group of people called a Human Research Ethics Committee (HREC) to make sure it is safe to do. This study has been checked and approved by the Western Australian Aboriginal Health Ethics Committee (WAAHEC) and Child and Adolescent Health Service (CAHS) HRECs. If you have concerns or complaints about the study you can contact them any time:



- WAAHEC HREC at [ethics@ahcwa.org](mailto:ethics@ahcwa.org) and (08) 9227 1631 or;
  - For CAHS HREC, The Executive Director Medical Services, on (08) 6456 2222

### What happens next?

If you want to ask any questions about the study, please talk to the clinic staff. You may also like to contact the Principal Investigator, Dr Asha Bowen or the project team. If you want to take part in the SToP study, we will ask you to sign a consent form.

You can keep this information sheet.



Dr Asha Bowen   Frieda Mc Loughlin   Rachael Donovan

Dr Asha Bowen, Telethon Kids Institute

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**Consent for ivermectin as treatment - this means you can say no**





**In saying yes to this study I agree that:**

- I have read the information sheet or someone has read it to me in a language that I understand and I have been able to ask my health care worker any questions I had. Any questions I had were answered.
- I understand the study and agree for myself/my child(ren) to participate. I understand I am free to stop at any time without this affecting my future care.
- I understand that if I withdraw from the study, the information already collected about me or my child/children will be kept and used in the study results.
- I can ask to have a copy of this signed form to keep if I want to.

**I confirm I consent to this study for myself:**


**YES NO**


 Taking the scabies pill medicine (ivermectin/Stromectol). I will take it 2 times over 1 week - today and again 1 week later.

 Study staff looking at my clinic records for up to 7 days after I take scabies pill medicine.

**I confirm I am the parent/carer and consent to this study for my child/children:**

**YES NO NA**

 My child/children taking the scabies pill medicine (ivermectin/Stromectol). They will take it 2 times over 1 week - today and again 1 week later.

 Study staff looking at my child/children's clinic records for up to 7 days after you they take scabies pill medicine.

**Participant Name:** \_\_\_\_\_ **Date of Birth: (DD/MM/YYYY)** \_\_\_\_\_

**Contact Details:** \_\_\_\_\_ **Signed:** \_\_\_\_\_

**Staff Name:** \_\_\_\_\_ **Signed:** \_\_\_\_\_

**Date: (DD/MM/YYYY)** \_\_\_\_\_

Child Full Name	Other Names	Date of Birth	School usually attends (if known)

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