What is a study?
A research study is what you do when you want to learn about something or find out something new.

Why is this study being done?
We are doing this study (called TREAT) to find out which is the best medicine to give children who have bad eczema.

What will happen to me if I take part?
1) If you are able, you will be asked to write your name on a form
This form is to say that you understand the study and what will happen. You will be given your own copy of the form to keep, as well as this leaflet. Apart from this, you do not have to do anything else. The doctors and nurses will do everything else for this study.

2) You will be asked to take a medicine and we will collect some information
If you take part in the study, you will be asked to take a medicine (as a tablet, liquid or an injection). A nice drink will be offered straightaway to help you swallow the medicine. This is to see if your eczema gets better. We will ask you if you can give us wee samples and blood sample at some visits. You can have a cream or spray to numb the skin before giving a blood sample if you like. We will also ask if you can give a saliva (spit) sample at one visit if we are not able to get a blood sample. The research nurse will also use some information from your hospital visits.
Do I have to say yes?

No – not at all. It’s up to you! Just say if you don’t want to join in. Nobody will mind.

If you change your mind, that’s ok as well, it will not change the way the doctors and nurses will look after you.

What shall I do now?

Now you know about the study you need to think about if you want to take part in the study.

Who can I ask about this?

Your mum or dad (or carer) have been given lots of information but if you have any questions or would like to speak to a nurse or doctor about this study then please ring: (INSERT NAME AND NUMBER FOR LOCAL NURSE)

Will the study upset or help me?

No - the study will not change how you are looked after at the hospital. We hope that the information we get from this study will help boys and girls who have bad eczema in the future.

Thank you very much for taking time to read this. Please ask any questions if you need to.
Assent Form for Children (6 – 10 years)

To be completed by the child and their parent/guardian

Please circle all you agree with:

(Child)

Has somebody explained this study to you?  Yes / No

Do you understand what the study is about?  Yes / No

Have you asked all the questions you want?  Yes / No

Have you had your questions answered in a way you understand?  Yes / No

Do you understand it’s OK to stop taking part at any time?  Yes / No

Are you happy to take part?  Yes / No

If any answers are ‘no’ or you don’t want to take part, don’t sign your name!
If you do want to take part, please write your name and today’s date

Your Name:  ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Today’s Date:  ~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Your parent or guardian must write their name here too if they are happy for you to do the study

Parent/Guardian Full Name:  ~~~~~~~~~~~~~~~~~~~~~~~~~

Parent/Guardian Signature:  ~~~~~~~~~~~~~~~~~~~~~~~~~

Today’s Date:  ~~~~~~~~~~~~~~~~~~~~~~~~~

The researcher who explained this study to you needs to sign too:

Researcher Full Name:  ~~~~~~~~~~~~~~~~~~~~~~~~~

Researcher Signature:  ~~~~~~~~~~~~~~~~~~~~~~~~~

Today’s Date:  ~~~~~~~~~~~~~~~~~~~~~~~~~

When completed, 1 (original) to be kept in researcher site file, 1 copy each for medical notes; for patient and for CTU, University of Liverpool