***To be printed on hospital headed paper***



**Are there any risks to me if I take part?**

The study will run alongside your routine eczema care and will not influence the way your

eczema is treated. Therefore, there are no additional risks associated with this study.

Your doctor may ask you to give a blood sample, but it is up to you if you want to do so. This blood sample will give us information of how your body is built, and help us understand what makes you different from people who do not have eczema.

A blood tests can be a bit uncomfortable and can cause some bruising or itching, but this is mild.

**A-STAR: The UK-Irish Atopic eczema Systemic TherApy Register**

**Why have you been invited?**

We have invited you because you are about to start taking a new medicineto treat your eczema.

We want to invite as many people as possible who are taking these medicines to take part.

**Why are we doing this study?**

We need more information on the effects of medicines that are used to treat eczema when taken for a short or a long period of time. Also, we want to study how quickly these medicines make your eczema better and improve patients’ lives. All participants will be followed up for at least one year, but ideally for longer.

We expect this information will help doctors to treat people with eczema in the future.

**Title of Project:** The UK-Irish Atopic Eczema Systemic Therapy Register (A-STAR)

**Name of Researcher**: Prof Carsten Flohr, Consultant Dermatologist, Guy’s & St Thomas’

 We would like you to take part in a research study.

 Please take time to read this leaflet carefully and discuss it with others if you wish.

 Ask us if anything is unclear, or if you would like more information.

 Take time to decide if you wish to take part.

**Many thanks for reading this information sheet.**

**YOUNG PERSON INFORMATION SHEET (Guide age 11-15)**

**What are the possible benefits of taking part?**

Although there is no benefit to you and you will not receive any incentives, the information we will get from this study may improve the treatment of patients with eczema in the future.

**Expenses and payment**

**You will be offered a voucher to the value of £10 per visit to cover reasonable expenses during the course of the study.**

**What will happen to the results of this study?**

The results of the study will be shown in our website, presented at scientific meetings and published in medical journals but no identifiable patient information will be used.

**Will anyone know I have been involved with this research?**

All information used in the study is kept under secure conditions and is strictly confidential.

**What information will we get from you?**

This type of study is called an ‘observational study’ which means that we simply watch what happens to people. The study does not affect the treatment that you get from your doctor.

The study will collect information about you, your eczema, medical treatment and tests, and how well you are for at least one year. We will also ask you to complete some questionnaires. The information we collect will come from the team you see for your normal hospital visits, and you will not have to come to the hospital any more often that you normally do.

The information on yourself, your eczema and the test results will be entered onto electronic databases. All this data will be kept secure and will only be accessed by A\*STAR study team members, or people who come to check that we are running the study properly. We plan to collect some personal information so we can link your details with other national databases, and find out some additional information about which your doctor may have missed out.

**Do I have to take part?**

You do not have to take part if you do not want to.

If you decide not to take part it will not affect how your doctors treat you.

If you **do** decide to take part, and your parents or carers agree, you and they will sign a form to show this.

You can change your mind at any time without saying why.

***Optional sub-study: Bio-repository***

This study will be done across many hospitals in the UK and Ireland. Some of these hospitals may collect some extra samples from you. If your hospital is one of these, the box below will be ticked as ‘yes’, and you can read this section. If the ‘no’ is ticked, you can jump onto the next paragraph:

Is this section relevant to me?

If you agree, we will collect some extra blood from your arm for other tests. We will collect this through a needle on 4 different occasions, always at the same time as your doctor collects your usual blood samples.

If you agree, we will swab your skin with a cotton bud to look for bacteria and biological molecules on 3 different days.

If you agree, we will collect skin cells with a cellotape on 3 different days.

You can decide which of these samples you want to give, but you don’t have to give any of these if you don’t want to. You can still participate in the other parts of the study. Also, if you agree to give any or all of these samples now, you can stop this collection later on.

 Some of these tests can be a bit uncomfortable and can cause some bruising or itching, but this is mild.

  After this study has ended we may still use this sample for future research of skin disease.

No

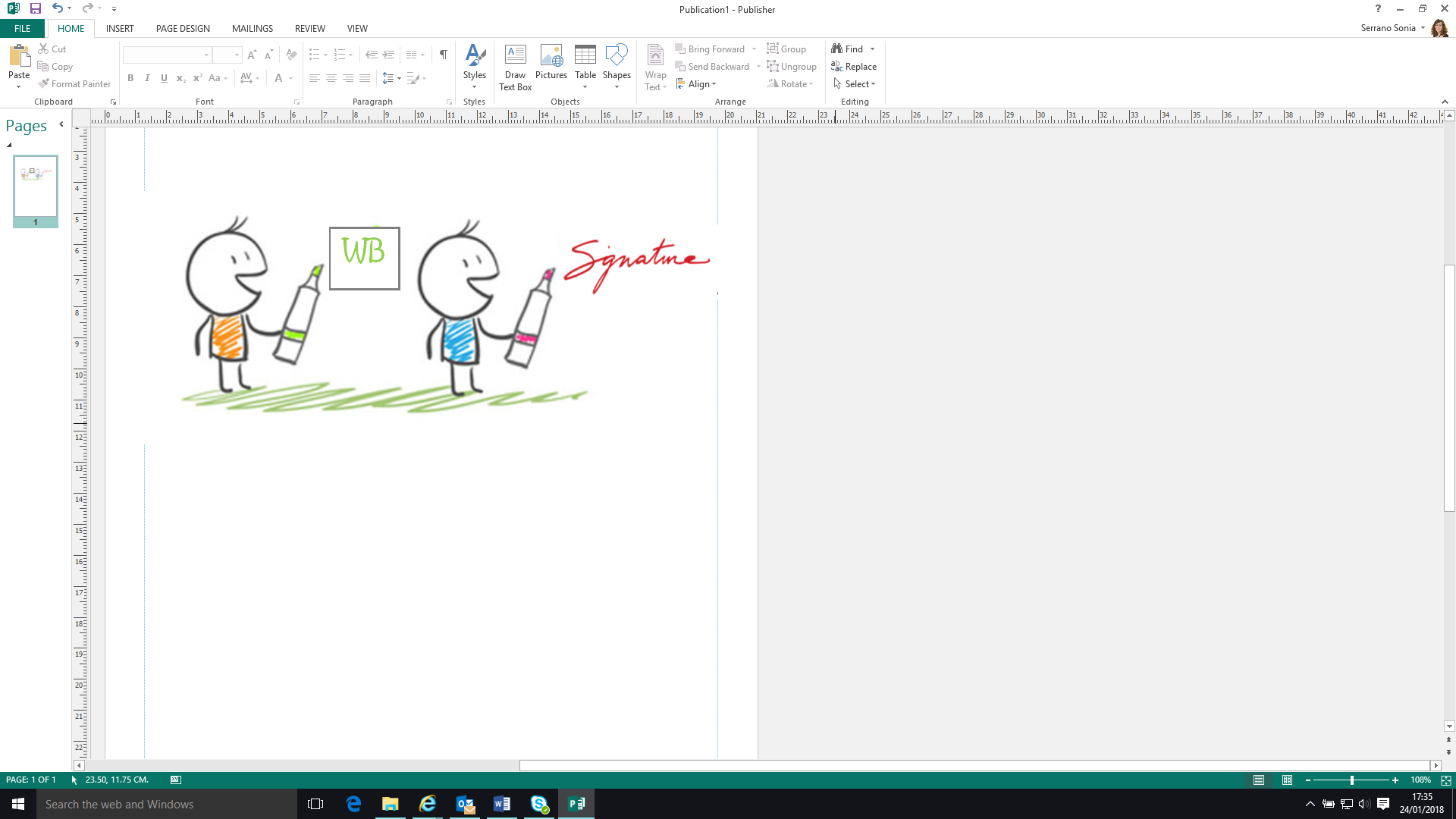
Yes

**Thanks for reading this information leaflet. If you do decide to take part in the study, you will be asked to sign an assent form. Your parent or carer will also be asked to sign a consent form.**

The research is based at the St John’s Institute of Dermatology at King’s College London/Guy’s and St Thomas’ Hospitals. If you want to ask about anything please get in touch with the Principal Investigator at your hospital.

You can find more information in our website:

**http://astar-register.org**







***To be printed on hospital headed paper***

PATIENT ASSENT FORM *(For individuals not legally able to agree to consent.*

*To be signed alongside a Parent/Guardian Consent Form)*



**A-STAR: The UK-Irish Atopic eczema Systemic TherApy Register**

Or cross if you don’t agree

Initial box to agree

WB

X

I have read the study

information

I was able to ask questions

about the study

I am happy to complete questionnaires

I know that I can stop taking part in the project at any time and it won’t affect my time in the hospital and the nurses and doctors will not mind at all

I was told what I

wanted to know

I am happy to give some blood samples for research

I agree for those samples to be used in future research

I want to take part in

the A-STAR study

I agree to give skin tape strips

**Your name:**

**Your**

**signature:**

**Date:**

I agree to give skin swabs

*1 copy for patient; 1 copy for researcher; 1 copy to be kept with hospital notes*