

PATIENT INFORMATION SHEET

**Title of Project: The UK-Irish Atopic eczema**

**Systemic TherApy Register (A-STAR)**

**OPTIONAL Biorepository Sub-Study**

What is the purpose of the biorepository sub-study?

As part of the A-STAR study, we would like to collect some blood and skin samples to help us understand how atopic eczema works and why some treatments work better in some people, or cause more side effects in others. However, this part of the study is entirely optional and you do not have to give any samples at all if you do not wish to.

Why have I been invited and what my contribution means?

You have been invited to participate to this sub-study as you have agreed to participate in the main A-STAR study.

Do I have to take part in this sub-study?

You do not have to take part; participation is entirely voluntary and your medical care or participation in the A-STAR study will not be affected regardless of your decision. If you do decide to take part, you can keep this information sheet and you will be asked to sign a consent form. By signing the consent form you would be confirming your willingness to take part.

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 sub-study.

What are the risks of taking part in the sub-study?

As part of this sub-study you will be asked to give additional blood samples and skin samples (through a biopsy and or swabs and or tape strips). You can choose which of these tests you want to have.

During the collection of the blood samples you may experience discomfort, and there is a risk of bleeding and bruising around the puncture site but this is very rarely serious. Complications of a biopsy may include: discomfort, infection, scarring, and very rarely reaction to the local anaesthetic used during the test, and bleeding from the site where the tissue sample (biopsy) is taken. There are no risks associated with the swabs or tape strips.

What are the benefits of taking part in the sub-study?

Although there is no additional clinical benefit gained by participation in this study, the information obtained from you will help the study team to better understand atopic eczema and to ultimately develop more effective treatments for future patients.

Will the research influence the treatment I receive?

The research does not alter the treatment you receive. Your specialist will start and stop treatments as determined by your clinical condition.

What will happen if I take part?

If you agree to participate in this part of the study, some or all of the samples mentioned below will be taken, depending on the hospital where you are based, and depending on your decision:

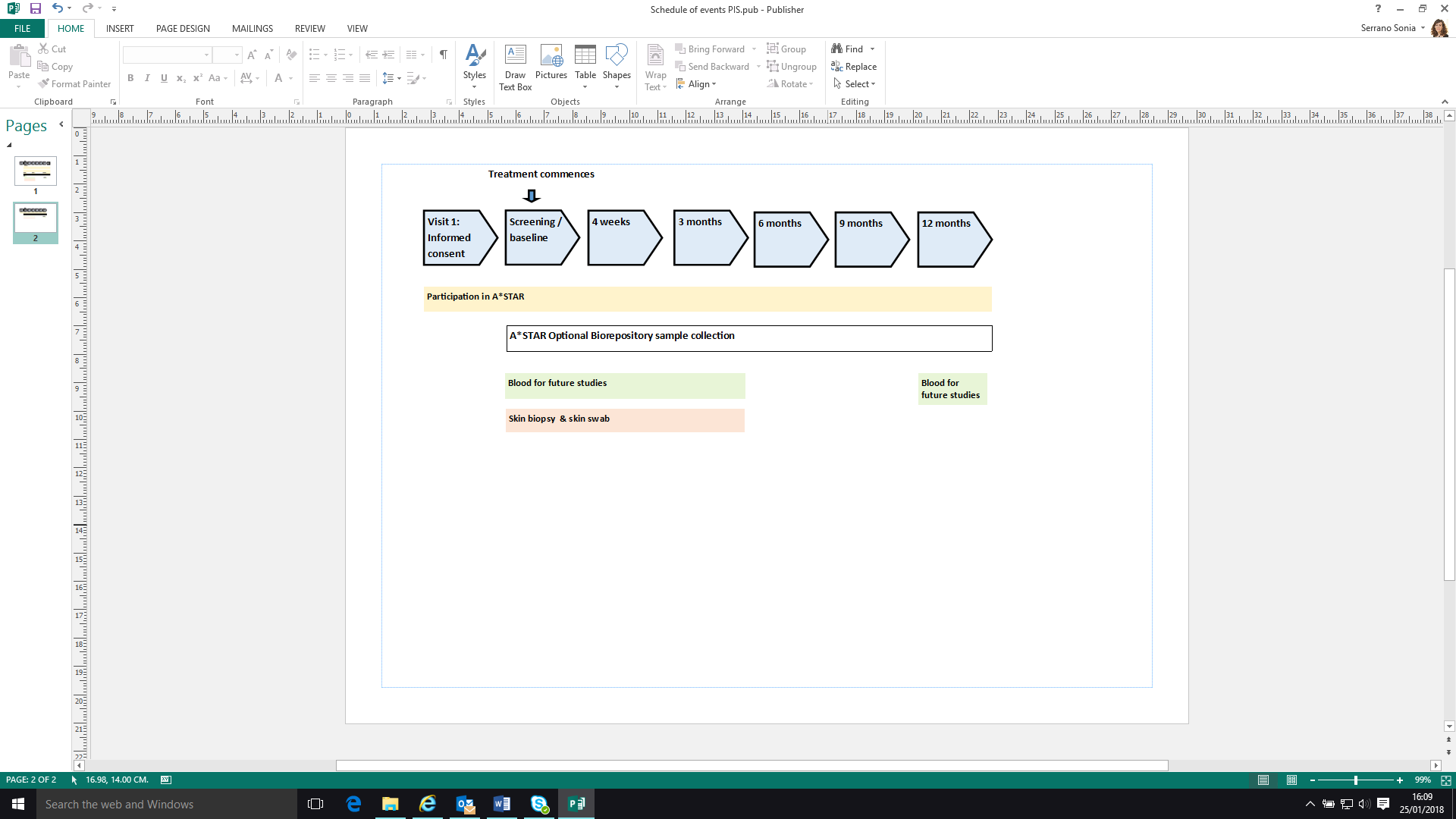
* 1. **Blood samples**: 40 ml (up to 7 tubes) of blood will be taken by drawing blood from your vein. Research blood samples will be taken on 4 different occasions.
  2. **Skin biopsies:** a biopsy is a procedure that involves taking a small sample of skin tissue so it can be examined under the microscope. Two biopsies will be taken on each occasion, one from inflamed and one from non-inflamed skin. Before taking the biopsies, the areas will be disinfected and injected with a local anaesthetic. Then, two pieces of skin of about 5 mm will be taken. The biopsy areas will require 2 to 3 stitches and will be covered with a dressing. Biopsy sites should not be allowed to get wet for the first 24-48 hours after taking the biopsy. You will need to have the stitches removed approximately 7-10 days later at your GP surgery or at the hospital where the biopsy took place.

Biopsies will be taken on 3 different occasions.

* 1. **Skin strip sample:** 8 sticky discs (like Sellotape) will be applied to the skin to take a small sample of skin so it can be examined under the microscope. This is not painful or uncomfortable. For patients donating skin biopsy samples an additional 8 samples will be taken from an area of skin close to the biopsy site. These will be taken on 3 different occasions.
  2. **Skin swab samples**: to identify the microorganisms and metabolites that are involved in eczema. The samples will be taken from inflamed and non-inflamed skin from near the same spot and immediately prior to the biopsies. There will be no specific after-care as this procedure will not puncture your skin.

Skin swabs will be taken on 3 different occasions.

Below is a chart that shows each of the study visits and what samples we would ask you to donate at each visit:



What will happen to my blood and skin samples?

We will look for different markers in your samples to help us increase our knowledge and understanding about eczema and the current treatments. Markers can be anything in the sample which tells us about your eczema or treatment. Some of these markers are genetic, so we will test the DNA in your samples. We will test for changes in genes, including filaggrin, which has a known link to eczema. We will also test the RNA (similar to DNA) in your samples, and this will tell us which genes are switched ‘on’ and ‘off’. We think this will help us predict how well you will respond to a treatment.

This study involves the collaboration of leading dermatology clinics, University research laboratories and industrial partners. All collaborators have specific expertise in analysing the samples we ask you for, and therefore the samples we obtain from you will be sent to a number of different research centres, and in some cases this may be outside of the UK/Ireland or even Europe.

All samples will be labelled by your local hospital staff, who will remove your personal details other than initials and store them securely at your local hospital’s laboratories, in accordance with the Human Tissue Act and to national and local healthcare Research Governance guidelines. Subsequently your samples may be analysed by your local hospital team, or shipped by courier or special post to another laboratory linked to the study (for example King’s College London). The researchers testing these samples will not have access to your personal details other than your initials and study number. The study number is the code linking your samples & clinical information. Only staff members involved in this project will have access to your samples. We plan to store your biological samples for the duration of this study. Afterwards we plan to store your study code, pseudo-anonymised information (this may include genetic data) and pseudo-anonymised samples for future research into skin disease. In the consent form you will be asked if you are happy to give permission for the storage and analyses of samples in future studies, not covered by the present research proposal. Such studies will have had to be approved by a Research Ethics Committee. If you do not consent to this point, your samples will be discarded at the end of this study.

Information on the Use of Data

**How we will use information about you**

We will need to use information from you and your medical records for this research project.

This information will include your:

* Name
* Date of birth
* NHS/hospital number
* Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure. Some of your information may be sent outside the UK. If your data is sent outside the UK our rules about keeping your information safe must still be followed.

The study uses electronic questionnaires hosted on OpenApp’s electronic case report form (eCRF) platform. They will process your data on behalf of KCL/GSTT and use reliable security measures that comply with NHS/University requirements. During this process, your data will be hosted in the UK and stored for a minimum of 5 years after the study end.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**Your choices about how your information is used**

* You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
* We need to manage your records in specific ways for the research to be reliable. This means you can’t see or change the data we hold about you.
* If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.
* If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation(s)) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to ask if you want to take part in another research study. You might then be asked if we can give your contact details to another research team within Guy’s and St Thomas’ NHS Foundation Trust or King’s College London. Agreeing to be contacted does not commit you to agreeing to take part in further studies.

**Further information on the use of your data**

This study will produce genetic data from your samples. We will not share genetic data with anyone intending to identify people with it. Researchers can apply to use this anonymised data in a secure environment and a data access committee will consider these applications. Only anonymised data will be released into the public domain.

There are many collaborators on this research. By signing the consent form, you are agreeing that your anonymised study data can be shared with research collaborators and industry partners, who may be located outside of the country or region in which you live. In some cases, other scientists around the world may be given access to the research data derived from your donated anonymised samples (this may include genetic data). Your study data will always be kept confidential, secure and will only be released to research collaborators in an anonymised form, and used only for the purposes of research.

**Where can you find out more about how your information is used**

You can find out more about how we use your information

* Visiting the Health Research Authority website at:

[www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)

* Visiting the Guy’s and St Thomas’ website at:

[www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx](http://www.guysandstthomas.nhs.uk/research/patients/use-of-data.aspx) (For GSTT)

and King’s College London website at:

<https://www.kcl.ac.uk/research/research-environment/rgei/research-ethics/use-of-personal-data-in-research> (for KCL)

* By asking one of the research team (contact details included below)
* By contacting the Data Protection Officer:

(For GSTT: Nick Murphy-O’Kane [DPO@gstt.nhs.uk](mailto:DPO@gstt.nhs.uk); For KCL: Olenka Cogias [info-compliance@kcl.ac.uk](mailto:info-compliance@kcl.ac.uk))

**Researcher contact details:**

If you have any further questions about the study please contact Tom Ewen on phone: 0191 208 753 or email: [Tom.Ewen@newcastle.ac.uk](mailto:Tom.Ewen@newcastle.ac.uk).

How do I withdraw from the sub-study if I want to?

You can withdraw at any time from the study after giving your signed consent by contacting your local dermatology research team. You will be given a withdrawal form where you can express your wish, which ranges from not giving any more samples, to the complete removal of your previously given samples. Unless you tell us otherwise, we will keep all the samples that we have obtained up until the point of withdrawal.

Who is organising the study?

The study is being co-­ordinated and sponsored by The St John’s Institute of Dermatology at Guy’s & St Thomas’ NHS Foundation Trust and King’s College London. The researchers at Guy’s and St Thomas’ Hospitals are Dr Carsten Flohr (A-STAR Chief Investigator) and Prof Catherine Smith, Consultant Dermatologists.

Where can you see the study results?

You can find further information about this study online: [http://astar-register.org](http://astar-register.org/). Regular updates and results of the research will be uploaded on this portal. Any study results or published reports using the data will be anonymised prior to publication, so that it is not be possible to identify you.

Study results will also be published in medical journals, as well as disseminated through the information channels of the British Association of Dermatologists. These will also be available to your consultant (contact details in the letterhead) whom you should contact for further information. Further details of your main contact is found on the main study information sheet.

PATIENT CONSENT FORM

**Title of Project:**

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

**OPTIONAL Biorepository sub-study**

1. I confirm that I have read and understood the information sheet dated  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (version \_\_\_)** for the above study and have had the opportunity to ask questions.

**Please initial box**

1. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected and without giving a reason. I understand that I can still participate in the main A-STAR despite my refusal/withdraw to have samples collected.

**Yes**

**No**

**Please initial ‘Yes’ or ‘No’ to the following optional sections:**

1. I agree to provide blood samples for research in this study.
2. I agree to donate skin swabs for storage and future analyses.
3. I agree to donate skin strip samples for storage and future analyses.
4. I agree to donate skin biopsies for storage and future analyses.
5. I agree for my DNA and RNA to be used for the purposes of research.
6. I agree for my anonymised data and samples to be used for the purpose of research by the consortium that may include commercial partners (for example drug companies).
7. I give permission for my samples and data to be sent to centres within and outside the UK.
8. I agree for any remaining blood or tissue samples at the end of this study to be stored in Research Tissue Banks and used in future studies in skin disease following the necessary Ethical approvals.
9. I am willing to be contacted in the future to be invited to participate in further research or clinical trials.

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| --- | --- | --- | --- | --- |
| *Name of patient* |  | *Date* |  | *Signature* |
|  |  |  |  |  |
| *Name of person taking consent* |  | *Date* |  | *Signature* |
|  |  |  |  |  |
| *Name of witness (if applicable)* |  | *Date* |  | *Signature* |
|  |  |  |  |  |
| *1 original for patient; 1 original for researcher; 1 copy to be kept with hospital notes* | | | | |