

PARENTS / GUARDIAN INFORMATION SHEET

**Title of Project:**

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

**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 your child does not have to give any samples at all if you or they do not wish to.

Why has my child been invited and what their contribution means?

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

Does my child have to take part in this sub-study?

Your child does not have to take part; participation is entirely voluntary and medical care or participation in the A-STAR study will not be affected regardless of this decision. If you do decide for your child to take part, you can keep this information sheet and you will be asked to sign a consent form, and your child will be asked to sign an assent form. By signing these forms, you both 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 your child will be asked to give additional blood and skin samples (through a tape strip and or a swab). You can chose which of these tests you want your child to have.

During the collection of the blood samples your child may experience discomfort, and there is a risk of bleeding and bruising around the puncture site but this is very rarely serious. There are no risks associated to the swab or the skin strip sample.

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 your child 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 my child receive?

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

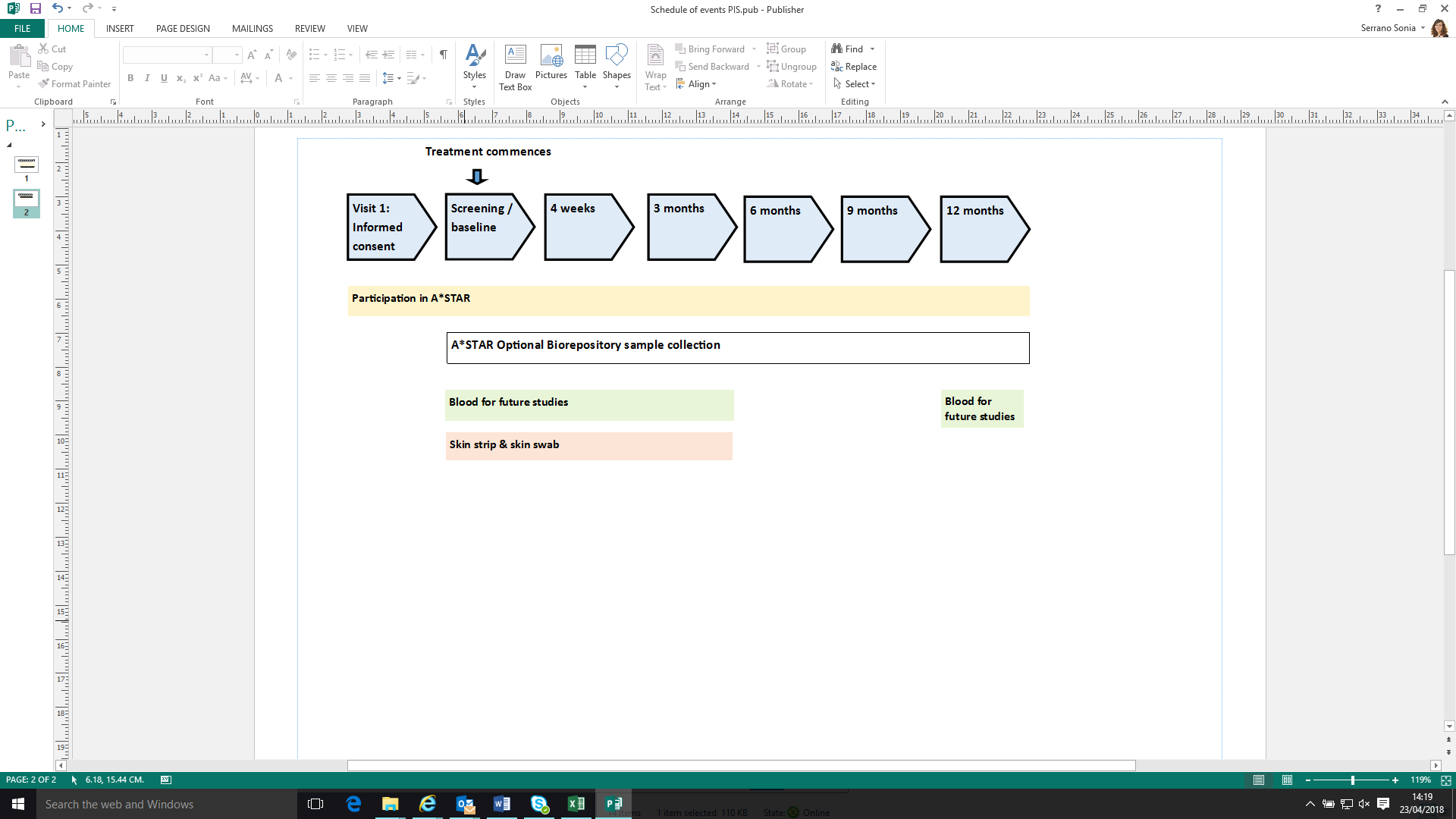
What will happen if we take part?

If you agree for your child 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**: blood will be taken by drawing blood from your child’s vein. Research blood samples will be taken on 4 different occasions and the amount will depend on the age and body weight of the child.
  2. **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. These will be taken on 3 different occasions.
  3. **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. Skin swabs will be taken on 3 different occasions.

There will be no specific after-care after the skin strip sample and the swab samples, as these procedures will not puncture the skin.

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



What will happen to the blood and skin samples?

We will look for different markers in these 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 child’s eczema or treatment. Some of these markers are genetic, so we will test the DNA in your child’s 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 child’s samples, and this will tell us which genes are switched ‘on’ and ‘off’. We think this will help us predict how well your child 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 for, and therefore the samples we obtain from your child 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 the local hospital staff, who will remove the personal details other than initials and store them securely in accordance with the Human Tissue Act and to national and local healthcare Research Governance guidelines. Subsequently the samples may be analysed by the 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 personal details other than the initials and study number. The study number is the code linking your child’s samples & clinical information. Only staff members involved in this project will have access to the samples. We plan to store the biological samples for the duration of this study. Afterwards we plan to store your child’s 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, the samples will be discarded at the end of this study.

Information on the Use of Data

**How we will use information about your child**

We will need to use information from your child and their medical records for this research project. This information will include your child’s:

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

People will use this information to do the research or to check your child’s records to make sure that the research is being done properly. We will keep all information about your child safe and secure. Some of your information may be sent outside the UK. If your child’s 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 child’s data on behalf of KCL/GSTT and use reliable security measures that comply with NHS/University requirements. During this process, your child’s 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 your child took part in the study.

**Your choices about how your child’s information is used**

* You can stop your child being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.
* We need to manage your child’s records in specific ways for the research to be reliable. This means you can’t see or change the data we hold about your child.
* If you agree for your child 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 for your child 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 your child wants 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 for your child to take part in further studies.

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

This study will produce genetic data from your child’s 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 child’s 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 child’s donated anonymised samples (this may include genetic data). Your child’s 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 we withdraw from the sub-study if we want to?

Your child can withdraw at any time from the study after giving signed consent by contacting their local dermatology research team. You will be given a withdrawal form where you can express both your wishes, which ranges from not giving any more samples, to the complete removal of the 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**. 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 the participants.

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 child’s 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 for my child to provide blood samples for research in this study.
2. I agree for my child to donate skin swabs for storage and future analyses.
3. I agree for my child to donate skin strip samples for storage and future analyses.
4. I agree for my child’s DNA and RNA to be used for the purposes of research.

1. I agree for my child’s anonymised data and samples to be used for the purpose of research by the consortium that may include commercial partners (for example drug companies).
2. I give permission for my child’s samples and data to be sent to centres within and outside the UK.
3. I agree for my child’s 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.
4. I am willing to be contacted in the future for my child 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* | | | | |