

BSACI Registry for Immunotherapy (BRIT)

Consent Form for Guardians of Children Under 16 (under 12 in Scotland)

Your child is being invited to take part in a patient registry for people receiving immunotherapy for allergies and urticaria. Before you decide whether your child should take part, it is important that you understand why this project is taking place and what it will involve.

Please take time to read the following information carefully and talk to others about it if you want to. You can also ask the doctors and nurses looking after your child if there is anything that you do not understand or if you would like any more information. Take time to decide if you wish your child to take part in this project.

Who is BSACI?

The British Society for Allergy and Clinical Immunology, or BSACI, is the only national professional and academic society representing the specialty of allergy. The BSACI began life as a small interest group for allergy doctors and has grown to include scientists, nurses, dieticians and psychologists. We have over 1000 members working across the NHS, universities, and private care including Allergy, Immunology, Paediatrics, ENT, Dietetics, Allied Health, Dermatology, Respiratory Medicine, and

Primary Care. Our aim is to improve the management of allergies and related diseases of the immune system in the United Kingdom through education, training and research.

What is the BRIT Registry and what is its significance?

A patient registry is a database or collection of information about people affected by a disease, or people having a specific treatment or operation. BRIT is the only registry in the UK for people being treated with immunotherapy. It is held on a secure internet-based database. BRIT keeps track of what treatment has been prescribed and any side effects or reactions from these medicines. It records the number of people receiving immunotherapy and where they are being treated.

Immunotherapy for tree, grass, venom, house dust mite, animal and peanut allergy is a highly specialised treatment. The aim of the registry is to help provide better care in future for people with allergies by showing the long-term benefits of immunotherapy and the need for increased access to these treatments. The information collected will also help consultants to maintain best practice.

In addition, the data from the registry will be used to help develop specialist immunotherapy around the UK and to review

the safety and effectiveness of these medicines.

What will happen if I take part?

Your child's data will be uploaded by the clinical team and, if you have agreed to be contacted by the registry, you will start to receive online questionnaires via email or text message. These will occur at regular intervals (every 3 or 6 months) . Many immunotherapy centres use paper questionnaires to monitor treatment, the online questionnaires will be very similar. We will also send a monthly newsletter with updates about the registry (if you are interested in receiving it).

Many forms of immunotherapy continue to provide benefit for a period after they have been stopped. This can be months, years or even lifelong, depending upon what treatment has been given. Once your child's treatment has finished, we will ask you if you would like to continue to receive questionnaires. Continuing to complete the questionnaires after the completion of your child's treatment helps us to monitor the long-term effectiveness of these treatments.

What information is kept in the Registry?

The information kept in the Registry is like the information that is recorded during visits to Clinic. It will include information that might identify your child to others. We will ask you to complete a form with these identifiers – so that you know exactly what is being included. It also includes details about allergies, the type of treatment and if the treatment was a success, based on the online questionnaires that you complete. It also lists any side effects from the medication that you or your child's doctor have reported.

Do I have to take part?

It is entirely up to you and your child decide to take part in the registry. You will be asked to sign a form and provide the personal information that you wish to be included in the registry. Your child's care will not be affected in any way if you decide not to take part.

Can I change my mind later?

Yes you can. You are able to opt out and withdraw from the registry at any time without giving a reason. Any information held about your child will be removed from the registry. In place will be a simple, unidentifiable number indicating that a patient has been removed. You are also allowed to request portions of your child's data be removed, such as contact information or any unique identifiers. If you want to withdraw any or all of your child's data from the registry, please contact your consultant or the registry administrator. Your child's information will be deleted within 30 days of receiving your request. Choosing to opt out or withdraw consent from the registry will not affect the quality of your care in any way.

What happens when my child turns 16?

Once your child turns 16 and is legally able to consent, you (the guardian) will be contacted by the registry administrator and asked to forward an online consent form to your child. If the form is not completed within 30 days of receipt, their data in the registry will be locked and you will stop receiving the questionnaires.

Will my child's information be kept confidential?

The BSACI is the professional society for allergy specialists and clinical immunologists in the UK. The data on the registry is owned by BSACI and managed by the registry steering

committee, which is made up of specialist doctors and nurses and patient representatives from the Anaphylaxis Campaign and Allergy UK.

BSACI control the data and most analysis will be undertaken by specialists of the Registry Steering Committee. Only anonymous data will be downloaded for analysis by the RSC.

All the information in the registry is held on secure internet servers behind an NHS firewall. It is managed in accordance with relevant data protection laws and ethical principles. The registry is managed by Dendrite Clinical Systems.

Only a few people will have access to the identifiable information stored about your child in this registry. Your child's consultant specialist and their clinical team will have access to the personal information stored about your child, so that they can easily update their records and see how treatment is working.

A very small number of experienced administration staff at BSACI (these are referred to as 'trusted third parties') will also be able to see Your child's personal information. This is to enable the information to be updated or deleted if you want to opt out, and to keep the system maintained in accordance with data protection laws.

Each registry participant will be given a unique number which does not identify them to others. This number will be used when the Registry data is analysed by the BSACI.

The registry has been paid for by some of the companies who provide immunotherapy treatments but they do not control or own the data.

Further information about how we handle your personal information is available in our

Privacy Notice. Ask your consultant specialist for a copy or contact the Registry.

What will happen to the data?

Other researchers in the UK and abroad may also request to use this important dataset. The RSC will review requests by other researchers and pharmaceutical companies to use the data collected by the registry. Only anonymous data will be downloaded for these purposes.

Thank you for taking time to read this information sheet and for considering taking part in the registry.

If you have any questions or require any further information, please talk to a member of the care team at your Allergy Clinic.

Contact the Registry:

If you have any questions about the use of your data or if you want your information to be removed or updated, please contact the registry administrator.

Email: brit@bsaci.org

Phone: 0207 501 3919

Thank you for taking time to read this information sheet and for considering taking part in the registry.

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Guardian and Child Consent / Assent Form

Statement	Initials
I confirm that I have read and understand the registry participant information sheet (contained in this packet). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that my child's participation is voluntary and that they/I are free to withdraw at any time, without giving any reason, without their medical care or legal rights being affected. If they/I withdraw their consent their data will be removed from the Registry	
I understand that information about my child collected from their medical notes and the registry may be looked at by a small number of responsible individuals from the NHS Trust / Private Hospital or the regulatory authorities. I give permission for these individuals to have access to their records.	
I have completed a Participant Identifiers Form (contained in this packet). I agree to this personal identifiable information being held by the registry. (You can also choose not to provide this information if you prefer.)	
If my child changes consultant or hospital during treatment, I agree to the transfer of their registry data to the new consultant. (The record will still be visible to the previous consultant but will only be active for the new consultant and their team.)	
I understand that non-identifiable information collected about me may be used to support other research in the future and may be shared anonymously with the regulatory authorities and the pharmaceutical company that holds the Marketing Authorisation for the UK, in the event of an adverse reaction, or with researchers in the UK or abroad.	
I agree for the registry to contact me to a) send me questionnaires: Yes <input type="checkbox"/> / No <input type="checkbox"/> b) send me newsletters about the registry: Yes <input type="checkbox"/> / No <input type="checkbox"/>	
I agree to take part in this registry.	

Please sign on reverse.

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Parental Consent

Name of Patient:		
Name of Parent:	Signature:	Date:
Name of Person Taking Consent:	Signature:	Date:

Child Assent

Name of Patient:	Signature:	Date:
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Please make one copy for the participant and file original in the patient's medical notes.

BSACI **do not** require a copy of this consent form.



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Participant Identifiers Form

To be completed by the participant or their parent / legal representative.

These details will be stored on the registry for access by your consultant and their team.

First Name:	
Family Name:	
NHS Number (if known):	

Can we record your NHS number (CHI number in Scotland) in the registry? Yes / No

Your Contact Info:

We would like to contact you by email and/or text message with periodic questionnaires. The purpose of these questionnaires is to track your child's quality of life, as well as their symptoms and the efficacy of their treatment over time. We ask for your phone number because many people find it easier to complete these questionnaires through a text message link. You can opt out of receiving these questionnaires at any time. Your contact information will not be shared with third parties.

Your Email Address:

Your Phone Number:

Can we contact you with questionnaires about your treatment?

Via Email: Yes / No

Via Text Message: Yes / No

Can we send you a monthly registry update to keep you informed about our progress (email only)? Yes / No

The following information will be used for analysis by the registry and is optional.

Date of Birth (DD/MM/YYYY):

**DOB will be used to calculate age then removed from database*

What is your child's current gender identity?

- | | |
|--|--|
| <input type="checkbox"/> Male | <input type="checkbox"/> Female |
| <input type="checkbox"/> Transgender Male/Transgender Man/Female-to-Male (FTM) | <input type="checkbox"/> Transgender Female/Transgender Woman/Male-to-Female (MTF) |
| <input type="checkbox"/> Genderqueer/Non-Binary | <input type="checkbox"/> Additional Category (please specify): _____ |
| <input type="checkbox"/> Choose not to disclose | |

What sex was your child assigned at birth on their original birth certificate?

- | | | |
|-------------------------------|---------------------------------|---|
| <input type="checkbox"/> Male | <input type="checkbox"/> Female | <input type="checkbox"/> Choose not to disclose |
|-------------------------------|---------------------------------|---|

Country of Residence:

<input type="checkbox"/> England (Greater London)	<input type="checkbox"/> Scotland
<input type="checkbox"/> England (outside London)	<input type="checkbox"/> Wales
<input type="checkbox"/> Northern Ireland	<input type="checkbox"/> Channel Island or Isle of Man
<input type="checkbox"/> Other (please specify): _____	

Home Postcode:

**Your postcode will be used to calculate the distance from your home to clinic and generate sociodemographic codes. The postcode will then be removed from analysis. You can give only the first part if you prefer, e.g. W2 or SO16.*

Please circle your ethnicity code from the list below.

A. White

1	English / Welsh / Scottish / Northern Irish / British
2	Irish
3	Gypsy or Irish Traveller
4	Any other White background (please write):

B. Mixed / Multiple Ethnic Groups

5	White and Black Caribbean
6	White and Black African
7	White and Asian
8	Any other Mixed / Multiple Ethnic background (please write):

C. Asian / Asian British / Asian Irish

9	Indian
10	Pakistani
11	Bangladeshi
12	Chinese
13	Any other Asian background (please write):

D. Black / African / Caribbean / Black British / Black Irish

14	African
15	Caribbean
16	Any other Black / African / Caribbean background (please write):

E. Other Ethnic Group

17	Arab
18	Any other ethnic group (please write):

*Coding for Ethnic Group is based on Office for National Statistics 2011 for UK wide data collection.

Thank you for completing this questionnaire. Please return it to your immunotherapy doctor or nurse.

This form should be filed in the medical notes once data has been entered in the Registry.

BRIT does not need a copy.