Appendix

Baseline Questionnaire – Recording accidental allergic reactions in children and teenagers (ReAACT)

Version 1 20th August 2018

1. Patient Registration

Name:

Registration Number: ________________ Hospital Number: ___________________

Tallaght ○ OLCHC ○

Gender: Male ○ Female ○

2. Reminder of inclusion Criteria

- Has the patient a diagnosis (new/existing) of type 1 food allergy to common food allergens; Cow's Milk, hen's egg, peanut, tree nuts, fish, kiwi, seeds?
- Diagnosis will require either (i) a clear history of a recent reaction (previous 6 months) clinically consistent with Type 1 allergy and a positive skin test >3mm or (ii) a history of a reaction in the past (not necessarily the recent past) and a skin test in the past 6 months to that allergen, of >7mm or(iii) a positive food challenge performed at The National Children's Hospital, or OLCHC in the past 6 months
- Is the patient Age 2 or above?

3. Enrollment

Date of Birth: ___/___/_________ Date Enrolled: ___/___/_________ Age: _________

Was Informed Consent given for this study? Yes ○ No ○

Data input by: Miranda Crealey ○ Aideen Byrne ○ Other ____________________________

4. Demographics and History Summary

Patient's country of birth: Ireland○ Other:_______________________________________

Ethnicity: Irish ○ Caucasian/non-Irish ○Afro-Caribbean ○Asian ○Other: _____________________

Was the patient ever breastfed? Yes No Unknown

Duration of breastfeeding: Less than 1 month○ 1-3 months ○ 3-6 months ○ >6 months ○

Patient Environmental and Medical History

Where does the patient live? Urban/City/Town○ Rural-isolated/farm dwelling ○

How many people ordinarily live in the house (circle)? 2 3 4 5 6 7 8 9

What are the patient's parents' occupations? Father _____________________ Mother ____________________

Single parent household? Yes ○ No ○ if yes Mother ○ or Father ○

How many siblings? (circle)? 0 1 2 3 4 5 6

Place in family eldest ○ middle child ○ youngest ○

5. **Summary of Personal History**

Does the patient have a known history of autism? □Y □N

If yes, details____

6. **Eczema**

Does the patient have a known history of eczema? Yes □ No □

If yes: Mild □ moderate/severe (use of mod/severe potent steroids regularly) □

Does the patient still have eczema? Yes □ No □

If yes: Mild □ moderate/severe □

7. **EOE**

Does the patient have EOE? Yes □ No □

Current medications:

	Yes	**No**
Swallowed budesonide	□	□
Oral steroids	□	□
Elimination diet	□	□

8. **Asthma**

Does the pateint have a diagnosis of asthma? Yes □ No □

Current medications:

	Yes	No
SABA	□	□
ICS	□	□
LABA/ICS	□	□
Montelukast	□	□
Aminophyline	□	□
Omalizumab	□	□

9. **Allergic rhinits**

Does the patient have allergic rhinitis? Yes □ No □

Current medications:

	Yes	No
Antihistamine po	□	□
INCS	□	□
INCS/INAH	□	□
Saline rinse	□	□
SLIT	□	□
IO AH/CG	□	□

10. Food allergy

- Foods patient has ***ever*** reacted to:
- . Food 1________ date of 1st reaction _______________
- Food 2_______ date of 1st reaction ______________
- Food 3_________ date of 1st reaction ______________
- Food 4______ date of 1st reaction ________________
- Other ____
- Pollen related food allergy Yes ☐ No ☐

  If yes, details____
- Most recent investigations (in last 6 months):
- Food 1: SPT date: ____________ Result: ___________________________________
- Food 2: SPT date: _____________ Result:
- Food 3: SPT date: ____________ Result: ___________________________________
- Food 4: SPT date: ____________ Result: ___________________________________
- Does the patient have a history of anaphylaxis? Yes ☐ No ☐
- If yes, which food? ____
- Which foods is the patient *actively* avoiding?
- ____

11. Education and adrenaline autoinjectors

Has the patient previously been advised to carry an AAI? Yes ☐ No ☐

Has the patient received AAI education by the allergy CNS? Yes ☐ No ☐

12. <u>Child care plan:</u>

Is the child attending:

	Yes	No	
Nursery/ creche	☐	☐	ratio of children to minder____________________________
Childminder (other house)	☐	☐	ratio of children to minder____________________________
Au pair/nanny (own house)	☐	☐	ratio of children to minder____________________________
Montessori/ preschool	☐	☐	ratio of children to minder___________________________
Primary school	☐	☐	ratio of children to minder____________________________
Secondary school	☐	☐	ratio of children to minder____________________________
After school supervision	☐	☐	ratio of children to minder____________________________

Does the school or childcare facility have a written food allergy policy? Yes ☐ No ☐

Does the school or childcare facility have hardcopy of the child's food allergy action plan? Yes ☐ No ☐

Does the school or childcare facility have 2 AAIs for the child? Yes ☐ No ☐

- If yes, where are the AAIs stored? ____

Have you been asked to sign a document by the school or childcare facility to administer your child's allergy medication?

Yes ☐ No ☐

13. <u>School /childcare facility eating plan:</u>

	Yes	No	Unknown
Does the facility have a food allergy eating plan?	☐	☐	☐

If yes:

	Yes	No	Unknown
Separate tables:	☐	☐	☐
Separate rooms:	☐	☐	☐
Nut free facility:	☐	☐	☐

Food preparation in childcare/school:

Is food prepared in the facility? yes ☐ no ☐ catered ☐

Does the facility have a policy for preparing food for allergic children? yes ☐ no ☐
Does your child eat food prepared in the facility? yes ☐ no ☐
Does your child bring food prepared at home? yes ☐ no ☐
Does your child eat food brought in by others into the facility? yes ☐ no ☐
Does the facility let you know in advance if this is happening? yes ☐ no ☐

17. **Sports activities**
What sports is your child involved in outside of school?

Soccer	yes	□	no	□	club Y/N	frequency (dys)_________
Gaelic football	yes	□	no	□	club Y/N	frequency (dys)_________
Hurling	yes	□	no	□	club Y/N	frequency (dys)_________
Rugby	yes	□	no	□	club Y/N	frequency (dys)_________
Tennis	yes	□	no	□	club Y/N	frequency (dys)_________
Swimming	yes	□	no	□	club Y/N	frequency (dys)_________
Ballet	yes	□	no	□	club Y/N	frequency (dys)_________
Other	_______________				club Y/N	frequency (dys)_________

18. **Is your child involved in any other activities?**

Cooking	yes	□	no	□	frequency (dys)_________
Arts/crafts	yes	□	no	□	frequency (dys)_________
Singing	yes	□	no	□	frequency (dys)_________
Scouts	yes	□	no	□	frequency (dys)_________
Other------					

19. **Social activities**

How many parties a year does your child attend? 3 6 9 12 15

How often does your child go to a friend's house? Everyday 3/week 1/week 1/2weeks 1/month never

Does your child eat food prepared in their friend's house? yes □ no □

Does your child go to discos/dances? yes □ no □

Does your child sleep over in a friend's house? 1/week 1/2weeks 1/month 1/3month 1/6month never

Does your child go out trick or treating at Halloween? yes □ no □

20. **Eating out**

How often does your child eat outside the home (other than school)?
>1/wk 1/wk 1/2wk 1/month 1/3month 1/6months never

How often do you eat out in restaurants/cafes?
>1/wk 1/wk 1/2wk 1/month 1/3month 1/6months never

Does your child eat out with their friends in eateries without you? yes □ no □
>1/wk 1/wk 1/2wk 1/month 1/3month 1/6months never

How often do you order takeaways?
>1/wk 1/wk 1/2wk 1/month 1/3month 1/6months never

How often does your child visit the cinema?
1/2wk 1/month 1/3month 1/6months never

21. Food labelling

Do you regularly read food labels? yes ☐ no ☐
Does your child avoid food “that may contain” an allergen? yes ☐ no ☐

22. Travel

How does your child travel to school?(circle)
Car with parent walk with parent walk with friends school bus public transport

Is there any plan for your child to travel abroad this year without you? yes ☐ no ☐

Have you any plans to take holidays over the next year?
Details--
Flight yes ☐ no ☐ buy food at airport? yes ☐ no ☐
Ferry yes ☐ no ☐

Prospective study of allergic reactions in children attending an allergy clinic

Information Leaflet for Parents and participants

Research team: Dr Miranda Crealey, Dr Aideen Byrne (principal investigator: PI)

Version 1, 05th August 2018

Please read this information carefully before deciding whether or not you/your Child wish/wishes to take part in this research. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

Every parent worries that their child with food allergy will have accidental reactions in places such as in school, at a friend's house or on holiday.

At present we do not know how common accidental allergic reactions are in food allergic children in Ireland. We also do not know where accidental allergic reactions regularly occur or what foods are most frequently involved.

The purpose of this study is to collect information on accidental allergic reactions from children (aged 2-16yr) attending the Dublin allergy clinics.

This study has received a grant from the National Children's Hospital Foundation.

Who is organising this study?

The study team is Dr Aideen Byrne and Dr Miranda Crealey. Dr Aideen Byrne is the consultant allergist and head of the allergy departments in The National Children's Hospital (NCH), Tallaght and Our Lady's Children's Hospital Crumlin (OLCHC). Dr Miranda Crealey is a specialist registrar training in allergy. She is completing this research study as part of a doctorate degree being completed through Trinity College Dublin.

Why has my child been asked to participate?

Your child has a food allergy. We are interested in finding out how common allergic reactions are in children with food allergies in Ireland. We are offering all children aged 2-16 years attending the Dublin allergy clinic the opportunity to take part in this study.

What will happen to my child if they take part?

On enrolment into the study, we will gather information about your child's food allergy. We will complete a questionnaire with you collecting information about your child's food allergy, medications, other allergic disease, family history and other demographic details. This will take approximately 15 minutes. We will review your child's previous skin prick test and blood results from their medical chart. Participation in this study does not involve any extra tests or additional visits to the hospital.

If during the study, your child has an allergic reaction to a food they are known to be allergic to, we will ask you to complete a short questionnaire at home. This will allow us to collect details of the reaction e.g. where and how it occurred, symptoms, treatment etc.

A member of the study team will contact you by phone or email every 3 months if we have not heard from you to check for allergic reaction.

If you prefer not to take part, or prefer your child not to take part, you/your child will receive exactly the same care as those children who do enrol.

Are there any benefits in my child taking part?

The benefit of taking part will be to children with food allergy (like your child) and their families as a group.

We do not know how common accidental allergic reactions are in allergic children in Ireland and where they tend to occur. This information will help us better advise food allergic children, like your child and their families on high and low risk environments, how frequent these reactions occur and what typical behaviours lead to them.

This information will also help us advise those in charge of child safety such as TUSLA, Department of Education and sporting agencies. The more children who participate, the more information we can gather.

Patients are not being paid to take part in this research.

Research results will not be sent to all participants routinely, but if you are interested, you can request copies of publications from the study team.

Are there any risks involved?

We are solely collecting information about your child's allergy and as such, there are no risks involved in taking part in this research.

Will my child's participation be confidential?

Your child's information will be kept safe within in the hospital. The information collected will only be used for the purpose of the study. Once the study is finished after 2 years, the data collected will be filed in your child's medical records.

The Information collected as part of the study will be published in a medical journal. No personal identifying data will be used in this publication.

The recognised Ethics Committees at OLCHC and NCH have approved this study.

What should I do if I want my child to take part?

You should tell the study team. You will then be asked to sign a consent form.

At your request, you/your child can be removed from the study at any time. On withdrawal, any data collected on your child will be filed in their medical case notes.

Please take as much time as you need to decide whether you are willing to have your child participate in this study. Remember that your decision does not in any way affect the medical care your child receives.

If you have any questions, please contact Dr Aideen Byrne at 01 4096013

Many thanks for taking the time to read this information sheet,

Miranda (miranda.crealey @olchc.ie)

Proforma for allergic reactions – Prospective study of allergic reactions in children attending allergy clinic

Date of reaction: ____________

- Please name the food that your child reacted to_________________________________
- If you are unsure please tick here ○
- If you do not know tick here ○

- Did your child: (please circle)
  1. eat/drink the food 2. Touch/contact with the food. 3.Do not know

- Quantity of food ingested (circle): lick bite mouthful teaspoon other ____________

- Was there any food being eaten by another person close to your child? Yes ○ No ○

  If yes, what food? ____

- Does your child have a known allergy to this food? Yes ○ No ○

- Was this an accidental ingestion? i.e. Where you/ your child previously aware that the food ingested contained the food your child is allergic to? Yes ○ No ○

- Reason for reaction:

Accident /unintentional did check ingredients but given wrong information (verbal or written circle) unknown didn't read label error in reading label manufacturing labelling error

- Onset of symptoms: immediate ○ 1hour ○ 2hour ○
  - ➢ 2hours ○
- Who was with your child at time allergic food was consumed? (circle all applicable)

  On their own With friends parent sibling(s) teacher/childminder relative sports coach other ____________________________

- Who gave your child the food? (circle): child themself friend Parent sibling teacher/child minder relative sports coach other ____________________

- Location of reaction (circle all that apply):

home restaurant fastfood takeaway cafe creche/preschool (details)------- montessori school after-school sports club food-market hotel shop friend's house party out of doors Airplane Airport other (please state) ______

- Where you on holidays? Yes ○ No ○

- What was the main activity your child was involved in at the time of reaction?

sun cream application, crafts, baking, sports other ____________

- Were there any animals present? Yes ○ No ○ if yes, describe: ____________
- What activities was your child doing in the 2 hours prior to the reaction?
- ____
- Was your child unwell with a cold/infection at time of reaction? yes☐ no☐

Table 1

Symptoms: Please tick any symptoms your child had during the allergic reaction			
Hives / sudden rash		Flushing (redness)	
Sudden Itch		Nausea/vomiting Abdominal pain	
Swollen /itchy Eyes		Difficulty breathing/wheeze	
Swollen lips		Cough	
Swollen face		fatigue	
Sneezing/blocked nose		Collapse/ loss of consciousness/extreme tiredness	
Itchy tingling mouth		Throat tightening	
Treatment: Please tick any treatment and medications that your child received			
People involved in treatment of reaction:			
Went to GP/ on call doc		Antihistamine by mouth	
Went to hospital A&E		Steroids (pink tablets) by mouth	
Stayed at home		Ventolin (blue) inhaler	
Called ambulance		Adrenaline autoinjector at home If yes, how many/who	
No treatment		Adrenaline autoinjector in hospital	

Appendix Y

Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF) Children aged 0-12 years

Instructions to Parents

- The following are scenarios that parents have told us affect children's quality of life because of food allergy.

- Please indicate how much of an impact each scenario has on **your child's quality of life** by placing a tick

  or an x in one of the boxes numbered 0-6.

Response Options

0 = not at all

1= a little bit

2 = slightly

3 = moderately

4 = quite a bit

5 = very much

6 = extremely

All information given is completely confidential.

This questionnaire will only be identified by a code number.

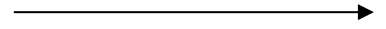
There are 4 sections to this questionnaire: A, B, C, and D.

- If your child is aged 0 to 3 years, please answer Section A ONLY
- If your child is aged 4 to 6 years, please answer Section A + Section B

SECTION A: For all age groups

Because of food allergy, my child feels……………	**0**	**1**	**2**	**3**	**4**	**5**	**6**
1 Worried about food in general	☐	☐	☐	☐	☐	☐	☐
2 Different from other children	☐	☐	☐	☐	☐	☐	☐
3 Frustrated by dietary restrictions	☐	☐	☐	☐	☐	☐	☐
4 Reluctant to try unfamiliar foods	☐	☐	☐	☐	☐	☐	☐
5 Concerned that he/she will have a reaction to food	☐	☐	☐	☐	☐	☐	☐

Because of food allergy, my child……………	**0**	**1**	**2**	**3**	**4**	**5**	**6**
6 Experiences physical distress	☐	☐	☐	☐	☐	☐	☐
7 Experiences emotional distress	☐	☐	☐	☐	☐	☐	☐
8 Has a lack of variety in his/her diet	☐	☐	☐	☐	☐	☐	☐



Because of food allergy, my child has been affected by………..	0	1	2	3	4	5	6
9 Receiving more attention more attention than other children of his/her age	☐	☐	☐	☐	☐	☐	☐
10 Having to grow up more quickly than other children of his/her age	☐	☐	☐	☐	☐	☐	☐
11 His/her environment being more restricted than other children of his/her age	☐	☐	☐	☐	☐	☐	☐

Because of food allergy, my child's social environment is restricted because of limitations on……..	0	1	2	3	4	5	6
12 Restaurants we can safely go to as a family	☐	☐	☐	☐	☐	☐	☐
13 Holiday destinations we can safely go to as a family	☐	☐	☐	☐	☐	☐	☐

Because of food allergy, my child's ability to take part has been limited……..	0	1	2	3	4	5	6
14 In social activities in other people's houses (*sleepovers, parties, playtime*)	☐	☐	☐	☐	☐	☐	☐
15 In preschool/school events involving food (*class parties/treats/lunchtime*)	☐	☐	☐	☐	☐	☐	☐

SECTION B : For children aged 4 to 12 years.

	Because of food allergy, my child feels…………..	0	1	2	3	4	5	6
16	Worried when going to unfamiliar places	☐	☐	☐	☐	☐	☐	☐
17	Concerned that he/she must always be cautious about food	☐	☐	☐	☐	☐	☐	☐
18	'Left out' in activities involving food	☐	☐	☐	☐	☐	☐	☐
19	That family social outings have been restricted by the need to plan ahead.	☐	☐	☐	☐	☐	☐	☐
20	Concerned about accidentally eating an ingredient to which he/she is allergic	☐	☐	☐	☐	☐	☐	☐
21	Worried when eating with unfamiliar adults/children	☐	☐	☐	☐	☐	☐	☐
22	Frustrated by social restrictions	☐	☐	☐	☐	☐	☐	☐

	Because of food allergy, my child…………..	0	1	2	3	4	5	6
23	Is more apprehensive in general than other children of his/her age	☐	☐	☐	☐	☐	☐	☐
24	Is more cautious in general than other children of his/her age	☐	☐	☐	☐	☐	☐	☐
25	Cannot be as confident as other children of his/her age in social situations	☐	☐	☐	☐	☐	☐	☐
26	Wishes his/her food allergy would go away	☐	☐	☐	☐	☐	☐	☐

SECTION C: For children aged 7 to 12 years

	Because of food allergy, my child feels…………..	0	1	2	3	4	5	6
27	Worried about his/her future(opportunities, relationships)	☐	☐	☐	☐	☐	☐	☐
28	Many people do not understand the serious nature of food allergy	☐	☐	☐	☐	☐	☐	☐
29	Concerned by poor labelling on food products	☐	☐	☐	☐	☐	☐	☐
30	Food allergy limits his/her life in general	☐	☐	☐	☐	☐	☐	☐

Section D : For all age groups

In the questions below, please tell us about YOUR opinion on the likelihood of each of the following events by placing a tick or an x in one of the boxes numbered 0-6.

	How great do you think is the chance that your child	**0**	**1**	**2**	**3**	**4**	**5**	**6**
1	will accidentally eat something to which he/she is allergic?							
2	will have a severe reaction if you/he/she accidentally eat something to which he/she is allergic?							
3	Will die if he/she eats something to which he/she is allergic?							
4	will effectively manage a reaction or will receive sufficient help from others if a reaction occurs ?							

5. How many foods must your child avoid because of food allergy?	6. How much has your food allergy limited the type of activities your child can take part in?
☐ almost none	☐ so little I don't actually notice it
☐ very few	☐ very little
☐ a few	☐ little
☐ some	☐ moderately
☐ many	☐ a good deal
☐ very many	☐ a great deal
☐ almost all	☐ a very great deal

Section E : For all age groups

	Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
1. **How confident do you feel about recognizing an allergic reaction in your child?**	○ Highly confident	○ Very confident	○ Confident	○ Somewhat confident	○ Not at all confident
2. **How confident do you feel treating your child's allergic reaction?**	○ Highly confident	○ Very confident	○ Confident	○ Somewhat confident	○ Not at all confident
3. **How confident do you feel about reading food labels?**	○ Highly confident	○ Very confident	○ Confident	○ Somewhat confident	○ Not at all confident
4. **How confident do you feel about identifying possible food cross contamination?**	○ Highly confident	○ Very confident	○ Confident	○ Somewhat confident	○ Not at all confident
5. **How confident do you feel that your child is safe at school, daycare, babysitters, or with relatives?**	○ Highly confident	○ Very confident	○ Confident	○ Somewhat confident	○ Not at all confident
6. **How confident do you feel that you can control your child's environment to prevent an accidental exposure?**	○ Highly confident	○ Very confident	○ Confident	◉ Somewhat confident	○ Not at all confident
7. **How confident do you feel about teaching others about your child's food allergy?**	○ Highly confident	○ Very confident	○ Confident	○ Somewhat confident	○ Not at all confident

	Highly confident	Very confident	Confident	Somewhat confident	Not at all confident
8. How confident do you feel that you have the resources and support you need to deal with your child's allergy?	○ Highly confident	○ Very confident	○ Confident	○ Somewhat confident	○ Not at all confident

FAQL-PB Food Allergy Quality of Life Parental Burden questionnaire

Food Allergy Quality of Life – Parental Burden questionnaire (FAQL-PB)		0 Not troubled	1 Hardly troubled at all	2 Somewhat troubled	3 Moderately Troubled	4 Quite a bit troubled	5 Very troubled	6 Extremely troubled
1	If you and your family were planning a holiday/vacation, how much would your choice of vacation be limited by your child's food allergy?							
2	If you and your family were planning to go to a restaurant, how much would your choice of a restaurant be limited by your child's food allergy?							
3	If you and your family were planning to participate in social activities with others involving food (e.g. parties, holiday, etc) how limited would your ability to participate in social activities that involve food be because of your child's food allergy?							
IN THE PAST WEEK . . .								
4	. . . how troubled have you been by your need to spend extra time preparing meals (i.e. label reading, extra time shopping, preparing extra meals, etc.) due to your child's food allergy?							
5	. . . how troubled have you been about your need to take special precautions before going out of the home with your child because of their food allergy?							
6	. . . how troubled have you been by anxiety relating to your child's food allergy?							
7	. . . how troubled have you been that your child may not overcome their food allergy?							
8	. . . how troubled have you been by the possibility of, or actually leaving your child in the care of others because of their food allergy?							
9	. . . how troubled have you been by frustration over other's lack of appreciation for the seriousness of food allergy?							
10	. . . how troubled have you been by sadness regarding the burden your child carries because of their food allergy?							
11	. . . how troubled have you been about your child's attending school, camp, day care, or other group activity with children because of their food allergy?							
12	. . . how troubled have you been by your concerns for your child's health because of their food allergy?							
13	. . . how troubled with the worry that you will not be able to help your child if they have an allergic reaction to food?							
14	. . . how troubled have you been with the worry that your child will not have a normal upbringing because of their food allergy?							
15	. . . how troubled have you been about concerns for your child's nutrition because of their food allergy?							
16	. . . how troubled have you been with issues concerning your child being near others while eating because of their food allergy?							
17	. . . how troubled have you been with being frightened by the thought that your child will have a food allergic reaction?							

For permission to use any of the above questionnaire(s), information, scoring, or advice on analysis of these questionnaires please email Audrey a.dunngalvin@ucc.ie