

About Food Protein-Induced Enterocolitis Syndrome

Written in collaboration by: The FPIES Foundation Board of Directors and Medical Advisory Board

Food Protein-Induced Enterocolitis Syndrome (FPIES) is a type of food allergy affecting the gastrointestinal (GI) tract. Classic symptoms of FPIES include profound vomiting, diarrhea, and dehydration. These symptoms can lead to severe lethargy, change in body temperature and blood pressure. Unlike typical food allergies, symptoms may not be immediate and do not show up on standard allergy tests. Furthermore, the negative allergy evaluation may delay the diagnosis and take the focus off the causative food. Nonetheless, FPIES can present with severe symptoms following ingestion of a food trigger.

FPIES Common Symptoms:

There are two ways that infants or children with FPIES might come to medical attention.

1. The classic pattern of an FPIES reaction is when a healthy infant or child develops symptoms shortly after eating a food. There is a characteristic delay of 2-3 hours before onset of severe and repetitive vomiting and eventually diarrhea. The child may appear very ill and sleepy (lethargic), and may become pale or blue. When evaluated by a doctor, he/she may be found to have low blood pressure, seem dehydrated, and have blood tests that mimic infection (sepsis); which in some cases can lead to sepsis-like shock. Many infants who are eventually diagnosed with FPIES are initially suspected to have a severe infection or sepsis.
2. The second common pattern of FPIES reaction symptoms occurs when infants who are ingesting a problem food (usually milk or soy-based formula or proteins in breast milk) as a consistent part of their diet might experience increasingly severe vomiting, diarrhea, and poor growth, possibly progressing to an illness mimicking a severe total-body infection. Please note that each child is unique and your child may experience their own range and intensity of these symptoms.

FPIES Common Triggers:

In the first months of life, FPIES reactions are most often caused by cow's milk protein formula, and sometimes by soy. Proteins in breast milk may also cause symptoms in some infants.

For infants experiencing FPIES with solid foods, rice and oats are the most common triggers. Current research reports other common triggers that include, but are not limited to, milk, soy, barley, poultry, peas, green beans, sweet potatoes, and squash. However, any food protein can be a trigger and some infants may be sensitive to other foods as well. In addition, some children may react to one or two foods whereas others may experience reactions to multiple foods.

FPIES Diagnosis and Testing:

FPIES is a non-IgE food allergy, which unlike classic food allergy, cannot be diagnosed with readily available food allergy tests such as skin prick test (SPT) or blood test that measure food IgE antibodies (RAST). These tests are helpful to identify triggers for typical food allergies that result in immediate hives, wheezing, and swelling and are characteristically **negative** in FPIES. An FPIES diagnosis is usually made by considering the history of the characteristic symptoms and exclusion of various alternative illnesses. A medical doctor, often an allergist and/or gastroenterologist, should be involved in making the diagnosis. Although Atopy Patch testing (APT) is often used for FPIES patients, it is not considered a validated test for FPIES diagnosis. Blood tests performed during a reaction may be helpful since the results often mimic the body's response to infection. The most definitive test is a medically supervised oral food challenge (OFC)-where the suspect food is given to the child in a controlled clinical environment. An oral food challenge, however, is not often needed initially if the doctor has excluded alternative illnesses and the medical history is consistent with FPIES.

FPIES Treatment and Course:

FPIES reactions can be severe. It is important to get to prompt medical attention where treatment, such as fluids given into the vein to help stabilize blood pressure and treat dehydration, can be given in order to avoid sepsis-like shock. Although some doctors prescribe epinephrine to stabilize blood pressure before medical treatment, the main therapy is to get intravenous fluids; also steroids can be used to quell the immune reaction. Preparing a letter for potential trips to the ER, containing both FPIES information and a list of your child's triggers, may be helpful.

Unfortunately, there are currently no simple tests for FPIES. The primary test, as mentioned above, is a medically supervised oral food challenge with the trigger food. The good news is that FPIES usually resolves with time. Your child will need to be closely followed by his/her doctor to discuss what foods are safe to eat and when it may be time to determine if FPIES has resolved. With proper medical attention and a personalized dietary plan to ensure proper nutrition, children with FPIES can grow and thrive.

About FPIES is a written collaboration of The FPIES Foundation Board of Directors and The FPIES Foundation's Medical Advisory Board: Sakina S. Bajowala, MD; J. Andrew Bird, MD; April Clark, RD/LD; John J. Lee, MD; Fred Leickly, MD, MPH; David R. Naimi, DO; Harumi Jyonouchi, MD; Scott H. Sicherer, MD; Anna Nowak-Wegrzyn, MD.

Additional Useful Resources:

1. Caubet, J.; Nowak-Wegrzyn, A. Current Understanding of the Immune Mechanisms of FPIES. Expert Review. *Clinical Immunology*. 2011; 7(3), 317-327
2. Jyonouchi, H. Non-IgE Food Allergy. Inflammation & Allergy. *Drug Target*. 2008; 7(3): 1-7.
3. Nowak-Wegrzyn, A.; Sampson, H.A.; Wood, R.A.; Sicherer, S.H. Food Protein-Induced Enterocolitis Syndrome Caused by Solid Food Proteins. *PEDIATRICS April 2003; 111 (4): 829-835*.
4. Sampson HA, Anderson JA. Summary and recommendations: classification of gastrointestinal manifestations due to immunologic reactions to foods in infants and young children. *J. Pediatr. Gastroenterol. Nutr.* 30(Suppl.), S87-S94 (2000).
5. Giovanna M., et al. Food Protein-Induced Enterocolitis Syndrome by cow's milk proteins passed through breast milk. *The Journal of Allergy and Clinical Immunology*. March 2011; 127 (3): 679-80.

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A Q&A Sampler: Questions from the FPIES Community, Answers from Our Medical Advisory Board (excerpts)

For expanded answers and additional topics, be sure to visit:

www.fpiesfoundation.org/fpies-questions-and-answers-from-the-medical-advisory-board/

My child was just diagnosed with FPIES— now what?

- 1) Get ready to go to school! The more you learn about your child's diagnosis, the better prepared you will be to serve as an advocate for his/her needs.
- 2) Prepare to partner with your physicians! Remember that you have a common goal – the health and happiness of your child. Find physicians you trust and with whom you can have open communication to help guide the way.
- 3) Get Support! Take advantage of the experience of parents who have walked in your shoes, and join a local or online support group for parents of children with FPIES. This support will be invaluable.
- 4) Get your family on board! Once you have a confirmed diagnosis, plan to sit down with key family members to help them learn about FPIES and how they can help your child stay safe and thrive.

I suspect FPIES, but what do I do if my child's doctor is not familiar with FPIES?

Because FPIES is an uncommon diagnosis, it is possible that your child's doctor may not be familiar with it. That's okay, and it is not an indication that you need a new physician. Let your doctor know what you're thinking in advance. Your physician deserves some time to educate herself about FPIES before offering an opinion. Consider a phone call, letter or email to your doctor to lay the foundation for the discussion, and include a copy of a recent medical journal review article on the topic. (Here's a suggestion: "The Current Understanding of the Immune Mechanisms of FPIES"). Ask if you can schedule an appointment to discuss the possibility of FPIES once your doctor has had an opportunity to review your child's chart and the literature.

What do I need to know about other conditions that may mimic FPIES?

In a young child, viral gastroenteritis with dehydration, sepsis (a severe infection) and anaphylaxis are conditions that may mimic FPIES during an acute symptomatic episode; abdominal surgical emergencies, such as intussusception or necrotizing enterocolitis (in infants), may also present similarly. These other diagnostic possibilities are important considerations and may lead to other diagnostic tests.

My child has additional symptoms not mentioned in the FPIES definition. Could he/she still have FPIES?

There can be variability in symptoms and they may not always match the "classical" descriptions. In severe FPIES reactions, shivering, fever or low body temperature were reported infrequently. Some children develop diarrhea with mucous or blood within 6 hours following an FPIES reaction. However, symptoms that start immediately (within minutes) following an ingestion of the food, such as itching, hives, sneezing or coughing suggest an IgE-mediated food allergic reaction, not FPIES. Remember that a child may have FPIES to one food and an IgE-mediated food allergy to other foods, or may develop sudden, IgE type reactions (hives, swelling, etc) to the FPIES trigger food. If you suspect that your child is reacting to a food, you should consult his/her pediatrician for advice and consider an evaluation by an allergist.

Why was my child able to eat his/her trigger foods one or more times before causing a reaction?

Often, allergic reactions, including FPIES do not occur on the first exposure to the offending food. Sometimes the immune system does not "attack" until there are repeated exposures. Nonetheless, there is frequently a reaction on the first "known" exposure, presumably because of some prior small exposures.

In what ways can I help my child during a reaction?

It is important to keep your child comfortable and get to medical attention for treatment. If your child has had prior severe FPIES reactions, is vomiting repeatedly, appears ashen-gray or lethargic, call 911 immediately. If you know your child ate their trigger food, you should head off to medical attention, such as an ER rather than a doctor's office, so that monitoring and potential treatments can begin promptly. If prior reactions were mild (such as 1-2 episodes of vomiting) and self-limited and your child appears comfortable and is no longer vomiting, oral rehydration with clear fluids or ice chips at home may be sufficient, but always speak with your doctor. Wait 10-15 minutes after an episode of vomiting and start offering small amount e.g. 1 tsp-1tbs of clear liquids every 5 minutes. Do not offer larger volumes of fluid because they may provoke more vomiting.

What can I expect at the first allergist and/or gastroenterologist appointment?

Be prepared to be asked many questions from your specialist. Your answers to those questions are essential because the diagnosis of FPIES is what is called a 'clinical diagnosis'. This term, 'a clinical diagnosis', refers to conditions where there is no definitive laboratory tests to confirm or make a diagnosis. In these instances, the doctor depends on the child's medical history to decide what is going on. What the specialist needs to know (you may want to write this down in advance of the appointment!)-

1. What happened? What were the symptoms experienced by the child?
2. What was the time course of the child's symptoms? What foods were involved?
3. How old was the child at the time of the event(s)?
4. How many times has this happened? Was it the same every time?
5. What was the timing from the exposure to a suspected food to the onset of the child's symptoms?
6. What was done to take care of the child? How long did it take for the child to recover?
7. What advice were you given about handling future events?
8. What tests have been done? Other questions will be asked to help rule out those other medical conditions especially infection or food allergy. The selection of tests may depend on whether or not the child is currently having an acute episode or is currently well and has recovered from the event.

What medical professionals are important in monitoring my child's care plan?

In addition to continuing your relationship with your child's primary care provider, the assistance of a Board Certified Allergist-Immunologist and/or pediatric Gastroenterologist will help to ensure your child is avoiding the food associated with his/her reaction. In addition to obtaining a thorough history, these specialists may need to perform one or more food challenges. Additional medical team members may include:

- A *Registered Dietitian* to assure that your child is receiving appropriate nutrition to reach his or her maximum growth potential and to provide education regarding safe dietary elimination.
- An *Occupational Therapist* or *Speech Therapist* may be necessary if your child requires feeding therapy secondary to an oral aversion he or she may have developed due to food restrictions.
- A *Social Worker* may provide direction and guidance obtaining coverage for medical expenses and medically necessary formulas. He/she can also point your family in the direction of an therapeutic services that may be needed.

What are the goals of long term management of FPIES?

- 1) To maintain proper nutrition
- 2) To obtain "safe" foods
- 3) To be ready to treat an accidental exposure that results in a reaction
- 4) To be monitored for possible resolution of the allergy with a goal to expand the diet if possible
- 5) To seek out a support system for the child as well as the family.

How do I safely provide foods for my child?

- *Learning to read ingredient labels* becomes an essential skill for families to safely prepare foods for a child with FPIES.
- *Mastering basic ingredient substitutions* and learning to modify familiar recipes can help to provide more dietary options
- *Learning your child's degree of sensitivity* and response to cross contaminants
- *When eating away from home*, consider doing research about the restaurant in advance and carrying allergy information cards when visiting the restaurant.
- *A registered dietitian may provide ideas* regarding avoidance of trigger foods and ensuring dietary needs are met.
- *When preparing to enroll your child in daycare or school settings*, you may consider:
 1. *Meeting with school professionals* to discuss your child's condition and degree of sensitivity.
 2. *Discussing with school professionals* the potential for food exposures throughout the day.
 3. *Drafting a formal plan* such as a 504 plan (based on your child's qualifications)
 4. *Preparing snacks and/or meals* with foods only from home.
 5. *Preparing an emergency plan* so that professionals know how to recognize an FPIES reaction in your child.



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www.thefpiesfoundation.org
contact@thefpiesfoundation.org

Helpful Medical Journal Articles

For an extensive, more complete listing of current and past literature, please visit:

www.fpiesfoundation.org/fpies-medical-literature

1. [Clinical Features and Resolution of Food Protein–Induced Enterocolitis Syndrome: 10-year Experience.](#) Caubet, Jean Christoph et al. Clinical features and resolution of food protein–induced enterocolitis syndrome: 10-year experience. Journal of Allergy and Clinical Immunology , Volume 134 , Issue 2 , 382 – 389.e4
2. [Clinical Presentation and Referral Characteristics of Food Protein-Induced Enterocolitis Syndrome in the United Kingdom](#) Ludman, Siân et al. Clinical presentation and referral characteristics of food protein-induced enterocolitis syndrome in the United Kingdom. Annals of Allergy, Asthma & Immunology , Volume 113 , Issue 3 , 290 – 294
3. [Food Protein-Induced Enterocolitis Syndrome: Pitfalls in the Diagnosis.](#) Guibas GV, Tsabouri S, Makris M, Priftis KN. Food protein-induced enterocolitis syndrome: Pitfalls in the diagnosis. Pediatr Allergy Immunology 2014:00.
4. [Chronic Food Protein-Induced Enterocolitis Syndrome Caused by Cow's Milk Proteins Passed through Breast Milk.](#) Miceli Sopo S, Monaco S, Greco M, Scala G, Chronic Food Protein-Induced Enterocolitis Syndrome Caused by Cow's Milk Proteins Passed through Breast Milk. Int Arch Allergy Immunol 2014;164:207-209.
5. [Nutritional management of food protein-induced enterocolitis syndrome.](#) Carina Venter; Marion Groetch. Current Opinion in Allergy and Clinical Immunology. Nutritional management of food protein-induced enterocolitis syndrome. Current Opinion in Allergy and Clinical Immunology. June 2014,p 255-262.
6. [Non-IgE-Mediated Food Allergy: FPIES.](#) Anna Nowak-Węgrzyn, George Konstantinou. Non-IgE-Mediated Food Allergy: FPIES. Current Pediatrics Reports June 2014, Volume 2, Issue 2, pp 135-143
7. [Clinical Management of Food Protein-Induced Enterocolitis Syndrome.](#) Sopo, Stefano Miceli; Iacono, Iride Dello; Greco, Monica; Monti, Giovanna. Clinical management of food protein-induced enterocolitis syndrome. Current Opinion in Allergy & Clinical Immunology. 2014 Jun;14(3):240-245
8. [Unmet Needs in Food Protein-Induced Enterocolitis Syndrome.](#) Wang, Julie; Fiocchi, Alessandro. Unmet needs in food protein-induced enterocolitis syndrome. Current Opinion in Allergy and Clinical Immunology. 2014 Jun;14(3):206-7.
9. [Feeding Difficulties in Children with Food Protein Induced Gastrointestinal Allergies.](#) Meyer R, Rommel N, Van Oudenhove L, Fleming C, Dziubak R, Shah N. Feeding difficulties in children with food protein induced gastrointestinal allergies. J Gastroenterol Hepatol. 2014 Apr 10.
10. [Food Protein-Induced Enterocolitis Syndrome, From Practice to Theory.](#) Stefano Miceli Sopo, Monica Greco, Serena Monaco, Salvatore Tripodi, Mauro Calvani. Food Protein-Induced Enterocolitis Syndrome, From Practice to Theory. Expert Rev Clin Immunol. 2013 Aug;9(8):707-15.
11. [Food protein-induced enterocolitis syndrome to trivial oral mucosal contact.](#) Mane SK, Hollister ME, Bahna SL. Food protein-induced enterocolitis syndrome to trivial oral mucosal contact. Eur J Pediatr. 2013 May 29.



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contact@thefpiesfoundation.org



Action Plan for FPIES

Child's name: _____ "Nickname": _____ DOB: ____/____/____

Primary language spoken: _____ Address: _____

Guardian: _____ Phone: _____ Guardian: _____ Phone: _____

Emergency Contact: _____ Phone: _____ Alt. Phone: _____

Classroom/Teacher: _____ Grade: _____ Contact Information: _____

Physician: _____ Phone: _____ Office/hospital _____

Physician: _____ Phone: _____ Office/hospital _____

Instructions when contacting physician: _____

Child's Allergens/Trigger Foods: _____ ☆ indicates history of shock

+ indicates history of additional
non-FPIES symptoms

At BASELINE my child: _____

MAINTENANCE strategies include: _____

Mild to Moderate Reaction Symptoms:

Symptom/ Set of Symptoms: _____

Intervention: _____

Symptom/ Set of Symptoms: _____

Intervention: _____

Symptom/ Set of Symptoms: _____

Intervention: _____

Severe Reaction Symptoms (See ER Plan for More Details):

History of Acute FPIES with Shock? Yes No History/High Risk for Anaphylaxis? Yes No

Emergency Medication? Yes No

Symptoms: _____

Intervention: _____



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FPIES Emergency Action Plan

Child's name: _____ "Nickname": _____ DOB: ____/____/____

Primary language spoken: _____ Address: _____

Guardian: _____ Phone: _____ Guardian: _____ Phone: _____

Emergency Contact: _____ Phone: _____ Alt. Phone: _____

Physician: _____ Phone: _____ Office /hospital _____

Physician: _____ Phone: _____ Office /hospital _____

Instructions when contacting physician: _____

Primary Physician's Requests: _____

Signed: _____

Child's Allergens/Trigger Foods:	_____	_____	☆ indicates history of shock
_____	_____	_____	+ indicates history of additional
_____	_____	_____	non-FPIES symptoms
_____	_____	_____	_____
_____	_____	_____	_____



FPIES (K52.21). Food Protein-Induced Enterocolitis Syndrome, is a type of food allergy affecting the gastrointestinal (GI) tract. Unlike typical food allergies, symptoms may not be immediate and do not show up on standard allergy tests. The symptoms of this type of allergic reaction include repetitive vomiting that may not start for a few hours (e.g., 2) following ingestion of the food to which the child is allergic. **Even trace amounts can trigger a reaction.** There is often diarrhea that starts later (after 6 hours). In some cases (about 20%), the reaction includes lethargy, hypotension, acidemia, and/or methemoglobinemia. **The treatment is symptomatic** and can include intravenous fluids (e.g. normal saline bolus, hydration) and steroids for significant symptoms. The latter is given because the pathophysiology is that of a T cell response. **This information is being given so that this could be considered in the differential diagnosis for this child in the event of symptoms.**

Alternately, some children affected by FPIES experience chronic reaction patterns independent of the acute reaction patterns. Though this reaction pattern does not typically require immediate emergency intervention, it can lead to serious consequences if left untreated and therefore must be appropriately reported to the provider if symptoms are observed. **These may include:** _____

Additional Diagnostic Information/Need for Testing: _____

Current Status (What's Happening NOW?): _____

Have you heard of FPIES?

FPIES is...

Food Protein-Induced Enterocolitis Syndrome, a rare but serious food allergy.

- **Food Protein-Induced** means that food protein "triggers" a reaction.
- **Enterocolitis** means the entire colon (GI tract) can be affected.
- **Syndrome** means the severity of symptoms vary from child to child.

Having FPIES means...

- Food can cause our children to be sick, some so violently ill they may go into shock.
- Although there are common "trigger" foods, any type of protein may cause a reaction.
- Avoidance of proteins that trigger a reaction is currently the only safe treatment.

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How can you help TODAY?

- Eat in designated areas only.
- Clean when you are done eating (even one crumb may trigger a reaction in a child with FPIES).
- Always obtain parental consent before feeding a child.
- Inform parents of a potential exposure **immediately**.
- Call 911 or "**immediately**" seek emergency medical help with a known reaction.
- Pass this valuable information along to everyone!

For more information on signs and symptoms of FPIES or how you can help, please visit:



www.thefpiesfoundation.org



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www.thefpiesfoundation.org



Have you heard?

*There are different
types of food allergies...*

Food Protein-Induced Enterocolitis Syndrome ("F-PIES") is a rare but serious type of food allergy.

- Symptoms of a reaction are delayed and may occur hours after exposure.
- Although there are '**common trigger**' foods, any food can cause an FPIES reaction.
- A severe FPIES reaction can include profuse vomiting, pale skin, extreme sleepiness (lethargy), diarrhea, dehydration, and can quickly lead to shock.
- Signs of shock for an individual with FPIES are severe and include lethargy, pale/grey skin tones, and drastic changes in body temperature and heart rate.

Call 9-1-1 or seek prompt medical attention in the event of a severe reaction that includes fluids or IV resuscitation. (Note: EpiPens will not stop an FPIES reaction.)

www.theFPIESfoundation.org

Currently, the only safe treatment for children with FPIES is avoidance of any food that triggers a reaction.

How can you help?

- **S**erve and eat foods in designated areas only, making sure to clean up any leftover foods immediately after finishing a meal or snack.
- **A**lways obtain parental consent before feeding a child.
- **F**ollow proper emergency procedures by informing parents of a potential exposure or calling 9-1-1 immediately if a severe reaction is suspected.
- **E**ducate others by passing this information along to everyone!

****Just one** crumb-sized portion of an allergen can trigger symptoms and put a child with FPIES at risk for a severe reaction**

*For more information, please visit
The FPIES Foundation @
www.theFPIESFoundation.org*





THE FPIES FOUNDATION INVITES YOU TO CONNECT

WE ARE PROUD TO INTRODUCE THE FIRST-OF-ITS-KIND, FPIES GLOBAL PATIENT REGISTRY. THIS REGISTRY WILL DEVELOP A STRONG FOUNDATION OF DATA, POTENTIALLY IMPACT EXISTING AND FUTURE RESEARCH, AND STRENGTHEN THE COLLECTIVE VOICE OF THE FPIES COMMUNITY.

FOR PATIENTS DIAGNOSED WITH FPIES
AND THEIR FAMILIES:



- PARTICIPATE IN SURVEYS TO FURTHER RESEARCH
- ALL INFORMATION IS PRIVATE AND DE-IDENTIFIED
- FREE REGISTRATION, FREE SURVEY ACCESS
- ABILITY TO VIEW INSTANT RESULTS!



FOR MEDICAL PROFESSIONALS SERVING
PATIENTS DIAGNOSED WITH FPIES:

- REGISTER TO JOIN THE DATA PORTAL!
- GAIN A BETTER UNDERSTANDING OF CURRENT TRENDS IN THE PATIENT COMMUNITY
- POST CLINICAL TRIAL NOTICES
- FREE REGISTRATION, FREE ABILITY TO VIEW DE-IDENTIFIED PATIENT DATA



CONNECT TO RESEARCH - CONNECT PATIENTS & PROFESSIONALS - CONNECT FOR CHANGE

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THE FPIES GLOBAL PATIENT REGISTRY IS
MADE POSSIBLE THROUGH THE PATIENT
CROSSROADS CONNECT PATIENT
REGISTRY PLATFORM.

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WWW.PATIENTCROSSROADS.COM

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The FPIES Global Patient Registry: An Introduction and Overview

In November 2013, we at The FPIES Foundation presented the first-of-its-kind FPIES Global Patient Registry, via the Patient Crossroads CONNECT program.

Some Key Terms:

- **Patient Registry:** Also referred to as a “disease registry” or “clinical registry,” a **Patient Registry** is a program that collects and stores data related to health information for a specific purpose and in an organized and uniform manner.
- **De-identified Data:** Information that is stripped of any and all identifying characteristics (name, email, etc) so that those viewing the data cannot see any connection to the participant from whom it came
- **Institutional Review Board (IRB):** this may also be referred to as an ethics review board. It is put into place in order to approve, monitor and review research that involves people-- it exists in order to protect research participants (<http://www.medterms.com/script/main/art.asp?articlekey=22413>)

There are two essential parts to the registry:

- **The patient registry**, which houses surveys (general questions and FPIES-specific questions) for registered participants to complete.
 - **General Surveys** will mainly utilize questions from the Patient Crossroads question library, a library of previously IRB-approved questions for use by any of the participating registry programs utilizing the CONNECT platform
 - **FPIES-Specific Surveys** will utilize questions engineered by The FPIES Foundation's medical advisory board, with support from the Executive Board. Those questions, once internally approved, will then be sent for approval by an IRB (Institutional Review Board) before being submitted to the Patient Crossroads CONNECT program for final approval and survey publication on the FPIES Global Patient Registry.
- **The data portal**, a newly released component of the CONNECT program, is for use by medical professionals, researchers, and other industry professionals (such as pharmaceutical companies). The portal is free for these professionals to register and allows them to view the de-identified, anonymous information entered into the patient registry by registry participants

How does the FPIES Global Patient Registry work?

The FPIES Global Patient Registry is set up through Patient Crossroads' Connect program-- a program offering platforms for rare disease organizations to create **registries** for their individual patient populations **and data portals** to display de-identified information from these registries. Registered participants, as well as registered medical, research and pharmaceutical professionals, can then view the information in a secured location. The registry is intended to present a “big picture” of FPIES and all of the issues that may or may not affect each individual patient. It aims to further research endeavors, examine improved treatments and achieve a better understanding of this diagnosis.


An important privacy feature of a research registry is the collection of data with de-identified information

De-identified information means that when you submit information into any of the surveys or the registration process of the Connect database, the information will not be able to be attached to you or your child's identifying characteristics. The information will be stored by means of a code, accessible only to Patient Crossroads staff. Even if you select the option to allow researchers to contact you, the contacting is done through Patient Crossroads. The researcher contacting you still does not have any identifying information about you, your child or even your contact information. All of those are protected, making this database secure and confidential. In

fact, its privacy standards are so high, the Patient Crossroads registry system is utilized by NIH (the National Institute of Health) to power its *Global Rare Diseases Patient Registry and Data Repository (GRDR)*!

How can I register today?

1. Go to the FPIES Foundation's home page (www.fpiesfoundation.org) and click on the blue "Connect" logo on the left side of the page
2. You will arrive at the home page for The FPIES Foundation Global Registry. Click the blue box that says "Click to Register Now!"
3. Complete the "Consent and Registration" section. Click "Register" and you are ready to go!
4. On your dashboard page, you will be able to select surveys to complete at your convenience. View the results as you complete each one and learn more about the FPIES community as you CONNECT!! Be sure to register each member of your family diagnosed with FPIES
5. **For PORTAL Registration**, simply go to the patient crossroads homepage at www.patientcrossroads.com and click on the button that says "log in/sign up" and follow the prompts!
6. For additional support, contact us at contact@thefpiesfoundation.org

	Patient Registry	Data Portal
What information can be viewed?	De-identified data from the FPIES Global Patient Registry	De-identified data from the FPIES Global Patient Registry
Who can register?	Individuals diagnosed with FPIES can be registered by their guardians to be survey participants	Medical professionals, researchers, industry professionals
How is my information protected?	<p>All information submitted by participants is de-identified-- this means that all identifying characteristics (name, contact info, etc) are removed from the information in the registry.</p> <p><i>In fact, the privacy standards are so high, the Patient Crossroads registry system is utilized by NIH (the National Institute of Health) to power its Global Rare Diseases Patient Registry and Data Repository (GRDR)!</i></p>	<ul style="list-style-type: none"> • All information submitted by participants is de-identified • If data portal participants wish to contact registry participants, Patient Crossroads does not disclose any information to these portal participants, but directs the communication to the registry participant without revealing any identifying info in the process. • Once contacted, it is the choice of the participant whether or not to reveal any information to the individual contacting them.
Why would someone contact me?	If you select the option to be contacted (this is part of the registration page-- you may opt in or opt out without your decision impacting your ability to participate in the registry) you may be contacted in regards to participation in clinical trials	

For more information and FAQ about the Patient Crossroads CONNECT program, go to:
<https://connect.patientcrossroads.org/en/home/frequently-asked-questions.html>



“...With the help of other FPIES families, we are coping, handling and even growing stronger as a family because of it” – An FPIES mom

FPIES (Food Protein-Induced Enterocolitis Syndrome) is a rare type of food allergy affecting the gastrointestinal tract. Classic FPIES reactions occur 2 or more hours after ingesting the “trigger” food and typically involve profuse vomiting, diarrhea, and can progress to shock.



There is no cure for FPIES and there are no diagnostic tests to confirm diagnosis. Food trials are the only way to determine whether or not a food is safe for each child. Any food can trigger an FPIES reaction and different children react to different food(s).

FPIES is not well-known, even within the medical community, and awareness is desperately needed to facilitate better diagnosis and symptom management for affected children. Together, we can raise awareness and help to improve the quality of life for affected children and their families.

The FPIES Foundation is an Incorporated 501(c)3 Non-profit Foundation whose mission is dedicated to overcoming the challenges of Food Protein- Induced Enterocolitis Syndrome by offering tools for education, support, and advocacy to empower families and the medical community.

www.TheFPIESFoundation.org