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“Designing a Food Allergy Research Database”

Food allergy is a worsening problem in the United States and affects 1 in 13 children. There is a significant economic and psychosocial burden associated with food allergy. Food allergy accounts for nearly 10,000 hospitalizations each year for children under 18 years of age. The current treatment for food allergy includes food avoidance and use of epinephrine for accidental ingestion. There are many emerging therapies for food allergy that are in clinical trials, including a recently approved treatment for peanut allergy. There are no clinical trials on food allergy being conducted at LSU Health Sciences Center/Children's Hospital New Orleans. The purpose of this study is to create a pre-consented database of patients with food allergy at Children's Hospital New Orleans. The database will provide an accessible resource for recruitment into retrospective or prospective clinical research studies pertaining to food allergy.

Subjects will be eligible for inclusion in the database if they are diagnosed with at least one food allergy by a provider at the Children's Hospital New Orleans Allergy Clinic. A diagnosis of food allergy requires both a convincing clinical history and evidence of sensitization to the suspected food allergen. The patients will be consented to include protected health information (PHI) in the database and to be contacted about inclusion in future clinical trials. All PHI will be stored in a Research Electronic Data Capture (REDCap) database. REDCap is a secure application designed to manage and store patient data. The PHI collected will include demographic information and clinical information relevant to the patient's food allergy (specific food allergen(s), skin prick test or serum IgE testing results, oral food challenge results). The patient will be contacted if they qualify for a future clinical research study.

The Institutional Review Board (IRB) application, consents, and assents have been completed and are awaiting submission to the IRB. The REDCap database hosted at LSU Health Sciences Center has been developed pending IRB approval. We expect to enroll approximately 100 subjects into the database over the study period. The development of this recruitment tool is an important step to becoming a study site in a clinical trial. This database will add value by allowing patients to access new treatments for a significant public health problem.