Boston Children's Hospital

RESEARCH CONSENT FORM

This section only to be edited by IRB office.

DO NOT PLACE IN MEDICAL RECORD

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title: Oral immunotherapy for cow's milk allergy

Principal Investigator: Dr. more than minimal risk

This consent form gives you important information about a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Please read this consent form carefully and take your time making a decision. The first section gives you an overview of the key information you should know about the research study. More detailed information about these topics may be found in the pages that follow.

The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

If the participant is a child the use of "you" refers to "your child"

Summary of Important Information

We are asking you to participate in this research study. Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not impact the clinical care you receive at Boston Children's Hospital.

In this research study we want to learn more about a study drug as oral immunotherapy for cow's milk allergy. Oral immunotherapy consists of taking daily small amount of the allergy-related food and increasing the dose gradually under medical supervision to help the body become used to cow's milk so that is no longer causes symptoms on exposure. The aim is NOT to cure cow's milk allergy, but hoping to protect against accidental exposures to cow's milk.

It is important to consider reasons why you would or would not want to participate in this research.

You do not have to be in this research study to be treated for cow's milk allergy. Your healthcare provider has discussed with you what your clinical treatment options are and which clinical treatment(s) might be right for you considering your medical history. These clinical treatment options include avoidance of cow's milk and treating accidental exposures and allergic reactions with medications. Each of the clinical treatment options has known rates of being effective, known risks, as well as possible drawbacks.

The study treatment has not yet been proven to be safe and/or effective for the treatment of cow's milk allergy. The study treatment may work better, the same, or worse and may have less, more, and/or other risks compared to the clinical care options. It is important to consider the trade-offs of the clinical care options as well as this research study before you decide whether you take part or not take part in this research study.

If you decide to join this research study, the following things will happen: You will be assigned by chance either to receive the active study drug or placebo (substance not containing cow's milk allergen). You have a 3 in 4 chance of being assigned to the active study drug and a 1 in 4 chance of receiving placebo. You will not know which group you are assigned to. If at the end of the study it is revealed you were in the placebo group, you may be eligible for a follow-on study where you will receive the active study drug. A separate consent form will be signed at that time.
Other study procedures include: 2 oral food challenges - each one spread out over 2 separate days, medical history, physical exam, questionnaires, blood draw incl. pregnancy testing, skin prick test, lung function test, asthma control test.

The most important potential risks to know about are anaphylaxis and eosinophilic esophagitis (where allergy cell inflame the food pipe). Other risks are mild to moderate allergic reactions including gastrointestinal symptoms, respiratory symptoms, and skin reactions and may require treatment or hospitalization.

The most important potential benefits to know about are that if you receive the active study drug, it is possible that your sensitivity to cow's milk allergy decreases while you are taking it. If you receive placebo, you will not directly benefit from taking part in this study.

It will take you up to one and a half years to complete this study. During this time we will ask you to make up to 30 study visits.

The research funds will cover cost associated with the study. We may bill your health insurer for routine items and services you would receive even if you did not take part in this research. You will receive up to $700 for the completion of the study. Some of travel related costs may be covered by the study.