

## What are my rights and responsibilities as a Protégé Encore study volunteer?

Those who join a clinical research study have certain rights and responsibilities. A doctor or nurse who is running the study will explain to study volunteers their rights and responsibilities.

For example, as a volunteer you have the right to:

- Talk to the study doctor about other kinds of treatment, which may include having usual diabetes treatment under the guidance of your own doctor without taking an investigational study drug or joining another clinical research study
- Be informed about all risks and benefits of the study
- Have access to study staff to answer all questions
- Be informed about new information relating to your safety or that may affect your willingness to continue participation in the study
- Have your health closely and frequently monitored
- Be able to leave the study if you no longer wish to participate

Study volunteers will also be asked to make a commitment to the study.

Responsibilities include:

- Following the study requirements, which include keeping study appointments, receiving the investigational study drug or placebo, and completing a diary card
- Answering study questions honestly

The Protégé Encore study is carefully designed to collect information and evaluate a potential new treatment for type 1 diabetes.

For more information on the Protégé studies, and to see if you may qualify for the Protégé Encore study, please call

[attach label with study site information]

[www.ProtegeDiabetes.org](http://www.ProtegeDiabetes.org)

Protégé  
Research to Protect Beta Cells  
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Just diagnosed with  
**type 1 diabetes?**

Take action.

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# Protégé Encore

A clinical research study to evaluate an investigational study drug that may help to slow or stop the progression of type 1 diabetes.

## What is the Protégé Encore study?

Your body uses a type of white blood cells, called T cells, to attack cells and germs that are foreign to your body. In type 1 diabetes, your body acts as if the insulin-producing beta cells in your pancreas are foreign and allows certain T cells to attack the beta cells. One way to slow the effects of type 1 diabetes may be to protect the beta cells from your body's attack. The Protégé Encore study is testing an investigational study drug called teplizumab, a CD3 monoclonal antibody that may protect the beta cells. Teplizumab is being compared to a placebo, an inactive substance that looks like teplizumab. Teplizumab may protect beta cells by binding to T cells before they can attack your beta cells.

## Why is the Protégé Encore study being done?

The Protégé Encore study is the second Phase 3 clinical trial testing the safety and effectiveness of teplizumab. The first clinical trial, called Protégé, has completed enrollment. Protégé Encore will further test whether teplizumab will reduce or prevent the autoimmune attack that damages beta cells. If it works and the remaining beta cells are preserved, some study volunteers may need less injected insulin, and blood glucose levels may be easier to control if the remaining beta cells are preserved.

## Who can join the Protégé Encore study?

To be in the Protégé Encore study, you must:

- Have had your first visit to a doctor for symptoms of type 1 diabetes and received that diagnosis within **12 weeks** of starting treatment on this study
- Be between **8 and 35 years** of age
- Weigh at least **36 kg** (5 st 9 lb)
- Not have had a vaccination with a live virus within **4-8 weeks** of study entry
- Not be using any other experimental treatment during the time you are in the study

The Protégé Encore study will enroll up to 400 volunteers at 100 or more medical facilities worldwide. Each volunteer's participation will last approximately 2 years.

## What will I be asked to do if I am in the Protégé Encore study?

MacroGenics, the manufacturer of teplizumab, is trying to determine whether teplizumab will protect beta cells in people with newly diagnosed type 1 diabetes. You (or your child) will be asked to:

- Confirm that you have had your first visit to a doctor for symptoms of type 1 diabetes within 12 weeks of starting treatment on this study
- Give consent for the study

- Have urine and blood tests to see if you qualify for the study
- Receive daily intravenous infusions of the investigational study drug or placebo for 14 consecutive days. This will happen twice: at the very beginning of the study and then again 6 months later.
- Attend follow-up visits in person or by telephone during the 2-year study commitment

## Why should I (or my child) consider joining the Protégé Encore study?

People with type 1 diabetes are prone to a number of complications from the disease. These include heart disease, kidney disease and blindness.

Study volunteers may or may not directly benefit from this study. What we learn from this study may help others at risk for type 1 diabetes. You will need to weigh the possible risks of taking the investigational study drug or placebo (which will be explained to you by the study doctor) against the possible benefits of participating in the study.

## **Study Sites Open in the United Kingdom**

**Aintree University Hospitals NHS Foundation Trust - University Hospital Aintree  
3rd Floor Clinical Sciences Centre, Longmoor Lane, Liverpool L9 7AL**

Study coordinator: Janet Cashen

Telephone: 0151 529 5940

Principal investigator: John Wilding

**George Eliot Hospital NHS Trust - Diabetes and Endocrinology Centre  
Lewes House, College Street, Nuneaton, Warwickshire CV10 7DJ**

Study coordinator: Amitha Gopinath

Telephone: 0247 686 5098

Principal investigator: Ponnusamy Saravanan

**Queens Medical Centre - Diabetes and Endocrinology Unit  
C floor South Block, Derby Road, Nottingham NG7 2UH**

Study coordinator: Judith Wallis

Telephone: 0115 849 3346

Principal investigator: Peter Mansell

**Guys Hospital - Clinical Research Unit, Dept of Diabetes and Endocrinology  
3rd Floor, Southwark Wing, Kings College, London SE1 9RT**

Study coordinator: Samantha Gillman

Telephone: 0207 848 4413 or 0207 188 1932

Principal investigator: Luigi Gnudi