What is this research study about?
You are being asked to be in this study because you are at increased risk of getting type 1 diabetes. People get type 1 diabetes because their immune system, the part of the body which helps fight infections, mistakenly attack cells (beta cells) that produce insulin in your body. As the immune system destroys these cells, the ability to produce insulin decreases and diabetes develops.

The goal of this study is to learn if teplizumab can help people at risk of getting type 1 diabetes by delaying or stopping destruction of beta cells.

This form tells you what will be done to see if you can be in this study. If the results of the screening tests show that you can be in this study, you will be asked if you would like to join the study. If you want to learn more about this study, you are welcome to read the full consent form and the patient handbook.

What does screening involve?

Oral Glucose Tolerance Test (OGTT)
You will have an OGTT to measure the level of glucose in your blood after drinking a sweet liquid that contains glucose. We will place a plastic tube with a needle (IV) in a vein in your arm. This IV will stay in your arm until the end of the test. Blood samples will be drawn through the IV before you drink the liquid and then several times after drinking it. This test will last 2 hours.

Urine Pregnancy Test (if you are female)

Tuberculosis Skin Test (PPD)
The PPD tests for a reaction to substances placed with a needle just under your skin. This test helps to tell us if you have had tuberculosis. You will need to have a qualified person look at the site where you received your injection in 48-72 hours to see if you have developed a reaction.

Storage of Blood Samples
With the permission of your parent(s), we would like to store any remaining blood samples. Your blood samples could be used to help researchers learn more about what causes type 1 diabetes and how to treat it better.
**Are there risks from being screened?**
When the IV is placed or your blood is drawn, there can be soreness or a bruise. Once in a while, people faint. It is rare, but some people may get an infection, a small blood clot or swelling of the vein and the area around it.

Sometimes a reaction to the material placed under the skin can happen from having a PPD test. You may develop a rash on your skin where the material was placed. The rash may be itchy and/or sore, but it will usually disappear within a few days.

**Will this study help me in any way?**
If you agree to have this screening done, you will find out if you meet the requirements to enter the study. If you qualify, we can’t promise that this study will help you. But it is possible that your pancreas could continue to make insulin for a longer time. We will follow your health and diabetes closely.

**Do I have to stay in the study?**
You don’t have to be in the study if you don’t want to. You can stop being in this study at any time.

**Can I ask any questions?**
You can ask us questions about the study any time. The staff of the research study will be happy to discuss any questions with you.

Child’s Printed Name: ______________________________________________
Child’s Signature: _____________________________ Date: _____________
Witness or Mediator: _______________________________________________
Date: _____________________________

I have explained the research at a level that is understandable by the child and believe that the child understands what is expected during this study.

Signature of Person Obtaining Assent: _________________________________
Date: _____________________________
INVESTIGATOR STATEMENT
I certify that the research study has been explained to the above individual by me or my research staff including the purpose, the procedures, the possible risks and the potential benefits associated with participation in this research study. Any questions raised have been answered to the individual’s satisfaction.

Investigator’s Printed or Typed Name: ________________________________

Investigator’s Signature: ________________________________

Date: ____________________