**Study Overview Template:**

**Greater than minimal risk:**

You or your child are being asked to take part in this research study because you have [DISEASE/CONDITION].

The purpose of this study is to find out if the study drug works better than current drug. The study drug is not approved by the FDA.

If you agree to take part, your participation will last for XXX and will involve XX study visits. You will need to take the study drug or placebo for XXX weeks. A placebo is an inactive substance. There are differences between this study and your usual care. As a participant in this research you will:

* Receive a study drug or a placebo; you will not know which
* Stop your regular medication
* Have X extra research clinic visits;
* Complete a double-blind food challenge;
* Have research blood tests, skin prick allergy tests, and other procedures.

The main risks of this study are from the study drug. These include: allergic reaction and skin irritation.

You may benefit if drug ABC or XYZ proves to be more effective. OR – You will not benefit directly from participating in this study.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time. If you do not choose to take part in this study, you can discuss treatment options with your doctor. You may also be eligible for a different research study (only if applicable).

Please see below for additional details about the study.