Partners HealthCare System
Research Assent Form

Subject Identification

Assent Template
Version Date: March 2013

Protocol Title:

Principal/Overall Investigator:

Site Principal Investigator:

Description of Subject Population:

We are doctors from **Brigham and Women's Hospital and/or Massachusetts General Hospital**. We would like to learn more about the best treatments for children who have a medical condition called **[insert name of medical condition]**. Children who have this condition **[insert explanation of medical condition]**.

To do this, we are asking you and other children with **[insert name of medical condition]** to take part in a research study. The results of the study will tell us if **[insert name of drug or treatment]** will help children who have **[insert name of medical condition]**.

If you agree, you will be asked to **[describe procedures using terms a child would know and understand – sample language which may apply to your study is provided below]**.

You will be asked to come to the Hospital to see one of the doctors doing this study **[insert how many times]**. The study will last for **[insert weeks/months/years]**.

You will have an equal chance of being given either **[study drugs]** or a placebo **[insert child's term for placebo],** and you will be asked to use it **[insert #of times during the day]** day for **[insert # of weeks]** weeks. If the medicine makes you feel sick we may need to take you out of the study.

We will draw blood from a vein in your arm **[insert how many times]**. You might feel a pinch when we use the needle to get some blood and this could leave a bruise (black and blue spot) where the needle was put into the vein.

We will ask you some questions about your **[insert]** and how it makes you feel. This should take about **[insert time it takes to answer questions]** minutes. You might get bored or tired when the doctor is asking you questions. You do not have to answer any of the questions we ask if you do not want to or if they make you feel uncomfortable.

When you go home, you will be given **[insert name of study medicine]**, the study medicine.

Someone will phone you after **[insert #]** days/weeks for a short talk and they will want to know how you are doing. This same interview will be done again in **[insert #]** days/weeks. Finally, we may call you back after about 3 months to see how you are doing and what medicines you are taking.

The medicines you take and the things that happen to you in this study may make you feel sick. **[Describe risks and discomforts using terms a child would know and understand.]**

We do not know if your **[insert name of medical condition]** will get better because you take part in this study, although we hope this happens. Some children may feel better because they are taking **[insert the active medicine].**

There are other ways to help your **[insert name of medical condition]** if you don't want to be in this study. Other medicines or tests can be used to treat **[insert name of medical condition].**

The information collected about you during this study will be kept safely locked up, and nobody will know who you are except the people doing the research. If we write an article about what we learn from the study, we will not use your name.

Before you decide to take part in this study, we will answer any questions you have. You can also talk to your mom or dad, or your doctor. You do not have to be in this study, it is okay to say no. If you decide to be in this study, you can change your mind and stop being part of it at any time.

You will be given a copy of this form to keep for yourself.

If you decide to be in the study, please sign your name below.

_____ _____

Subject's Signature Date

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