

**Participant Assent Form (Children ages 7-13)**

**Adjunctive CElecoxib in Childhood-onset OCD (ACE-OCD) Study**

**Invitation**

I am being invited to be part of a research study. A research study tries to find better treatments to help children like me. It is up to me if I want to be in this study. No one will make me be part of the study. Even if I agree now to be part of the study, I can change my mind later. No one will be mad at me if I choose not to be part of this study.

**Why are we doing this study?**

This study will help researchers learn more about a drug called celecoxib. Celecoxib is being tested to find out if it helps children like me who have a medical condition called obsessive compulsive disorder, or OCD. Children who have OCD often have upsetting thoughts or feelings (obsessions) that become so big that they make them do things they do not want to do (compulsions). Because of these obsessions and compulsions, kids often have difficulty doing fun and important things, like playing with friends and going out with family. Even though completing certain actions makes them feel better for a while, the upsetting thoughts and feelings keep on coming back. This study is trying to find out whether celecoxib can be added to other treatments to help with these problems. I am being invited to be a part of this study because in the past my doctor has decided that I have OCD, and it still causes problems for me.

**What will happen in this study?**

If I agree to be in this study, I will participate in a phone call together with a parent to answer questions about my health. Then we will go to see a study doctor (at BC Children’s Hospital or on the computer using videoconference) three times, for up to one hour each. Before and after the visits with the doctor, my parent and I will answer some questions about my health on the computer. Before or after I see the doctor the first time and the third time, a needle will be used to take a sample of my blood (1 tablespoon) for some tests to make sure it is safe for me to take the medication in this study. My height and weight will also be measured either at home or by a doctor, and my blood pressure will be measured by a doctor or research team member using a cuff that briefly squeezes my arm. I will be given the medication to take home, or it will be sent to my home. I will not know whether this medication is the one being tested in the study (called celecoxib) or one that looks the same but does not contain the drug, which it is being compared to (called a placebo). I will take this medication twice per day (morning and evening, with food) for 12 weeks. If the medicine makes me feel bad, then doctors will ask me to stop taking the medicine. I will continue to receive my usual treatments for OCD during this time.

**Who is doing this study?**

**Dr. Evelyn Stewart** and other doctors from BC Children’s Hospital and the Provincial OCD Program will be doing this study. If I need to talk to someone or have any questions, I can call Boyee Lin or Cynthia Lu at **(604) 875-2000 (ext. 3068)** or email them at aceocd@bcchr.ca. If I am having problems or there is an emergency and I cannot talk to my parents I can also call the doctors at **604-809-6622** (Dr. Stewart) or **778-837-4946** (Dr. Westwell-Roper).

**Can anything bad happen?**

Sometimes medicines make people sick or not feel very good. The doctors do not know very much about how celecoxib might work in children with OCD. But they do know that some of the children who have taken celecoxib for other reasons have stomach aches or feel like throwing up, especially if they do not take the medication with food. Even though the medicine is being tested for the treatment of OCD, I might not actually feel better during the study. It is possible I might feel worse. I should tell my parents right away if I feel worse.

I will also have to answer some questionnaires during this study. I may feel uncomfortable when I am asked questions that are hard to answer, but I am allowed to not answer any questions without explaining why. I may be nervous about doing the treatment or seeing the doctor. My parent(s) will be there to help me and I will not have to do anything that I do not agree to do.

**What should I do if I am not feeling well?**

If this medicine makes me feel bad or if I notice any strange or bad feelings during the study, I should tell my parents right away. I can also call one of the study doctors: Dr. Stewart at **604-809-6622** or Dr. Westwell-Roper at **778-837-4946**. I can call at any time, day or night, to tell them about how I feel. During the day, I can call the study members Boyee Lin or Cynthia Lu, at **(604) 875-2000 (ext. 3068)** or email themat **aceocd@bcchr.ca.**

**Could I get better by being in this study?**

No one knows whether or not I will get better by being in this study, and I may get worse. The study doctors hope that I will get better, but they cannot tell me that I will get better

**Are there any other treatments for me?**

If I am already receiving treatment for OCD, I will continue to receive it during this study. I do not have to be a part of this study to continue receiving any other treatments that are available. I can ask my doctor or my parents about any other treatments and therapies.

**Who will know if I am in the study?**

Only my doctors and people who are involved in the study will know I am in it. My information will be kept private. When the study is finished, the doctors will write a report about what was learned. This report will not say my name or that I was in the study. My parents and I do not have to tell anyone I am in the study if we don’t want to.

There may be times when information about me may be made known if I am in danger to others or myself, as decided by the study doctor. The study doctor could contact 911 (if there is a concern for harm likely to occur at any moment), contact a child welfare worker (if there is a concern about my safety in the home or in need for protection), or refer me and my family to the nearest emergency department.

If I am unable to meet face to face with people involved in the study or don’t want to, I can meet them online on a program called Zoom. Even though there is a chance that health information might be seen or accidentally be sent, the research team has done several things to keep my identity safe. These include using a version of Zoom that belongs to the university or the hospital, that joining Zoom needs a code that I will know before the meeting, that the link to the Zoom will be known only by people involved in the study, me, and/or my family, and the session will not be recorded. I will also be asked some questions about the answers I gave in the study to make sure it’s really me when meeting on Zoom. I will also be asked where I am in case of an emergency, while the study doctor will also tell me where he/she is. The study team will also go through with me of times when information about me may be made known.

I should use a nickname or a fake name, and not my real name, when joining Zoom. If I want, I can also turn off my camera and microphone. But there will be times I will be asked to turn on my camera and/or microphone by the research staff on Zoom to make sure of the data that I am giving.

**When do I have to decide?**

 I have as much time as I want to decide to be part of the study. I have also been asked to discuss my decision with my parents.

**If I put my name at the end of this form, it means that I agree to be in this study.**

Printed Name of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_