*Submit Consent Documents in **Microsoft Word ONLY*** *Leave blank for IRB Office Use.*	***IRB Office Use Only:*** Approval Date: Approved Consent IRB Version No.: PI Name: IRB No.

National Institutes of Health (NIH)
Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN)
ASSENT FORM FOR STUDIES INVOLVING CHILDREN

Study Title: Losartan for the Treatment of Pediatric NAFLD (STOP-NAFLD): A Phase 2, Randomized, Placebo-Controlled Clinical Trial

Principal Investigator:

IRB No.:

PI Version Date: 21 May 2018

Purpose of the study

We want to tell you about a research study we are doing. Research allows us to collect information from people to help us answer questions about health. We would like to find out more about testing a treatment for a liver problem in children called Nonalcoholic Fatty Liver Disease (NAFLD). Your liver is an organ, inside your body near the stomach area. This problem happens when too much fat stays in parts of your liver.

Why you are being asked to join the study

You have been asked to join because you have this liver problem. The reason for this study is see if a medicine called losartan will make this liver problem better**.** We hope to include about 110 other children like you in this study.

Procedures

If you agree to join this research study, you will be asked to make 7 visits to this research center over the next 10 months. At these visits you will do the following:

- Answer questions about your health and feelings.
- Have a physical examination to check your body including your liver.
- Fill out forms about what you drink, how you feel about your life, and how you are feeling.
- Take one capsule of medication each morning for one week, then take two capsules of medication or "sugar pills" (called a placebo) for this study once a day for 24 weeks. There is a 50/50 chance of getting the placebo.
- Listen to advice about nutrition and exercise and ask questions if you have any.
- Give blood samples.

Risks

There are some risks to being in the study:

Blood draw:

You will feel a pinch from the needle when you get your blood drawn and you may get a bruise where the needle was poked into your arm.

Study medication (losartan potassium):

The study medication may cause you to:

- have low blood pressure;
- feel dizzy;
- have a headache;
- have a fast heartbeat;
- feel anxiety;
- have a runny nose;
- have a sore throat;
- have to urinate more often

Risk to a baby:

There are risks to an unborn baby if you become pregnant during the STOP-NAFLD Trial. Use of the study drug losartan during pregnancy can cause injury and death to the developing baby. Potential negative effects to the baby include incomplete development of the skull and lungs (skull and lung hypoplasia), the baby's kidneys do not make urine (anuria), low blood pressure (hypotension), kidney failure, and death. If you decides to take part in this study, and have periods, you must be as sure as possible that you are not pregnant. It is important that you contact the study doctor right away if you think you may be pregnant, if you have missed a period or if it is late, or if you have had a change such as heavier bleeding than usual or bleeding between periods. If you become pregnant during the study, you will stop taking the study drug.

Benefits

We do not know if being in this study will help you, but we hope to learn something that will help other children with liver disease.

Voluntary participation

You do not have to join this study. It is up to you. You can say okay now, and you can change your mind later. All you have to do is tell us. No one will be mad at you if you change your mind.

Do you have any questions?

If you want to be in this study, please sign your name. You will get a copy of this form to keep for yourself.

_____ _____

(Sign your name here) (Date)

_____ _____

(Signature of Person Obtaining Assent) (Date)