(Once approved, IRB logo goes here)	Approval date: Approved Authorization IRB version No.: IRB Study No:

INSTRUCTIONS FOR DRAFTING

A HIPAA COMPLIANT MEDICAL RECORD RELEASE FORM FOR RESEARCH

The purpose of this form is to have the participant identify those health providers from whom you need the participant's medical records for your research. You will send this form to those providers that the parent/legal guardian names to execute the authorization. It is important that the parameters around the request be clearly spelled out – what records do you need, and for what time period?

This form may be used in conjunction with a consent form with a HIPAA Authorization and/or a consent form without a HIPAA Authorization. If you are obtaining informed consent inside a U.S. covered entity, you should use the combined consent/authorization form. If you are obtaining informed consent outside of a covered entity, you may use the consent form without the HIPAA authorization.

- Please complete all the sections indicated.
- Delete this page.

(Once approved, IRB logo goes here)	Approval date: Approved Authorization IRB version No.: IRB Study No:

Authorization for Release of Protected Health Information (PHI) for Research

Medical Record Release Form

(from Pediatrician to Principal Investigator, and from Principal Investigator to Pediatrician)

Principal Investigator:

IRB Study No.:

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

Sponsored by: National Institutes of Health (NIH) and the Nonalcoholic Steatohepatitis Clinical Research Network (NASH CRN)

Participant Name: _____

Date of Birth: _____

We are asking you to authorize the disclosure and use of your child's private health information (PHI) for this research study.

The people who may receive or use your child's PHI include the researchers and their staff. The Health Care Providers listed below are required by the Federal Privacy Rule to protect your child's PHI. By signing this Authorization, you permit them to release your child's information to the researchers for use in this research study. The researchers will try to make sure that everyone who needs to see your child's private information for this research keeps it confidential, but we cannot guarantee this. Although the researchers may not be covered by the Federal Privacy Rule, they will make an effort to protect your child's information using the same standards.

Some other people may see your child's PHI outside of the research team. They may include the sponsor of the study, study safety monitors, government regulators, and legal compliance staff. All these people must also keep your child's information confidential.

You do not have to sign this Authorization, but otherwise your child may not join the study. It is your choice.

(Once approved, IRB logo goes here)	Approval date: Approved Authorization IRB version No.: IRB Study No:

Your Authorization does not have an expiration date; it will continue as long as the research continues. You may change your mind and take back this Authorization at any time. If you take it back, the researchers may still use the PHI they have collected about your child to that point. To take back the Authorization, you must contact the researcher.

I hereby give my authorization for:

_____

Name of doctor(s) and/or health care provider(s)

_____

Address of doctor(s) and/or health care provider(s)

To provide information from my child's medical records between:

DATE_____ and DATE_____

My child's health information may be sent to:

PLEASE INCLUDE STUDY CONTACT INFORMATION HERE

Parent/Legal Guardian Printed Name | Parent/Legal Guardian Signature | Date

NOTE: A COPY OF THE SIGNED AUTHORIZATION MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT'S PARENT; AND IF APPROPRIATE A COPY OF THE SIGNED AUTHORIZATION MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD.