PARENTAL PERMISSION
Study Title: Intravenous Nutrition and Liver Problems in Newborn Infants with Gastrointestinal Surgical Problems

Investigators: Sanjiv B. Amin M.D, M.S,

Introduction:

This consent form describes a research study and what you may expect if you decide your baby will participate. You are encouraged to read this consent form carefully and to ask the person who presents it, any further questions you may have before making your decision whether or not to have your baby participate.

This study is being conducted by Dr. Sanjiv B. Amin of the University of Rochester's Department of Pediatrics.

You are being asked to allow your baby to participate in this study because they are receiving intravenous nutrition including fat, glucose and protein as part of their routine care.

Purpose of the Study:

The purpose of this study is to learn more about the effects of the fat given as part of intravenous nutrition on the liver. Intravenous nutrition is required because feeding by mouth is not possible at this time. Your baby will need intravenous nutrition until we are able to provide all nutrition by mouth which may vary from a few days to several weeks or longer. Nutrition is necessary to help your baby grow, heal, and improve the function of the intestine.

The use of intravenous nutrition may be associated with injury to liver. The main components of intravenous nutrition include protein, fat, and glucose but we do not know which of these three components is associated with liver injury. Liver injury is evaluated by measuring bilirubin concentration in the blood. We routinely evaluate for this complication once every week when babies are on intravenous nutrition.

Newborn babies usually receive 1 to 2 gm/kg/day of intravenous fat to provide enough calories to grow, develop, and heal. We believe that fat intake may have a bigger role in causing liver injury however this has not been proven. With this study we plan to compare two different amounts of fat intake (both within the range of what is normally given) with respect to the development of liver injury.

Description of the Study Procedures :

If you agree to have your baby participate in the study, the following things will happen:

1. Your baby will be randomized into one of the two study groups described below. Randomization means that the group assignment will be chosen by a matter of chance (just like flipping a coin). One group will receive fat intake as part of intravenous nutrition at a lower dose (1gm/kg/day) and the other group will receive fat intake at a higher dose (2gm/kg/day). You will not be informed which group your baby has been assigned to.

2. Your baby will continue to receive their assigned dose of fat intake until your baby no longer require intravenous nutrition or has received it for 6 weeks, or develops signs of liver injury (whichever occurs first). If your baby develops signs of liver injury, your baby will receive the standard care for this problem and the fat intake will be at the discretion of the clinical care team.

3. A research team member will review certain parts of your baby's medical records and collect information about your baby's hospital course, problems, feeding, growth, medications, laboratory results and other significant events. By signing this consent you are giving your permission for the research team to request and receive this information about your child's medical conditions and course.

4. All the laboratory tests and other procedures needed for the study are already a part of the standard care in our NICU, so this study will not require any extra blood work or procedures. We would also like to store a sample of your baby's blood for future research on intravenous nutrition and its effects on the liver. We will only collect blood that is leftover from blood draws that are done as part of your baby's regular care. No extra blood will be drawn for the purposes of this study.

Allowing the study team to store your baby's blood is optional. You may still participate in the study without providing permission for blood storage. If you decide now that your baby's blood can be used for future research, you can change your mind at any time. If you do change your mind, please contact Dr. Sanjiv Amin at 585-2732696. Any blood that remains at that time will then be discarded. Samples that have been already used or any data that has been generated as a result of testing done on your sample will not be able to be retrieved or destroyed. You will be asked to indicate your preferences regarding blood storage at the end of this consent form.

Number of Subjects:

We expect to enroll about 52 babies over the next two and half years.

Risks of Participation:

Intravenous fat is routinely given to babies to provide necessary calories for growth and development. Liver injury is extremely common among newborn babies who receive intravenous nutrition beyond a few weeks. We do not anticipate additional risk of liver injury other than what is normally observed in babies with the same problems as yours. Liver injury usually resolves once the intravenous nutrition is stopped. However, if your baby develops liver injury secondary to intravenous fat intake, the clinical team will be informed and your baby will be removed from the study. The fat intake your baby receives thereafter will be at the discretion of the physician treating your baby.

Every effort will be taken to protect your and your baby's privacy during the study. To protect the privacy of subjects, all links to subject identifiers will be decoded by assigning your baby a study number. Subject data will also be stored in a secure manner and only research team members will have access to this information. If you decide to allow us to store your baby's leftover blood, the sample will be labeled only with a subject number and stored indefinitely

within the Department of Neonatology. Only study team members will have access to these samples.

Benefits of Participation:
Your baby may or may not benefit from being in this study.

Compensation for Injury:
If your baby is directly injured by the drugs or clinical procedures solely required to participate in the study, you may need to pay for treatment of their injuries, but you will not be required to pay for emergency medical treatment provided at Strong Memorial Hospital or Highland Hospital. The University may seek payment for this care from your baby's health insurer or third parties. Decisions regarding care and compensation for any other research related injury will be made on a case-by-case basis.

Alternatives to Participation:
If you do not participate in the study, your baby will still receive intravenous fat intake of 1 to 2 gm/kg/day to provide calories. The amount of fat intake they receive will be at the discretion of the physician treating your baby.

Costs of Participation:
You and/or your baby's insurance provider will be responsible for the costs of the regular medical care, including the costs of intravenous nutrition, your baby receives during their hospital stay. There are no additional costs for participation in this study.

Confidentiality of Records and HIPAA Authorization:
Information identifying your baby as a participant in this study will become part of their Strong Memorial Hospital electronic medical record.

While we will make every effort to keep information we learn about you and your baby private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your child's name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) require us to get your permission to use health information about your baby that we either create or use as part of the research. This permission is called an Authorization. We will use your baby's research record, related information from your child's medical records, results of laboratory tests and both clinical and research observations made while your child takes part in the research.

We will use your baby's health information to conduct the study, to determine research results, to monitor your baby's health status, and possibly to develop new tests, procedures and commercial products. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy health information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you and your baby with the following people: The University of Rochester, the Department of Health and Human Service and the Food and Drug Administration (FDA).

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your baby's participation will be kept for 5 years after completion of the study and the publication of the findings. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, your baby will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others. By Federal law, we must send study information to the FDA for drug studies it regulates. Information that may need to be reported to FDA cannot be removed from your research records.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your baby's health information as stated above.

Contact Persons:

For more information concerning this research or if you feel that your child's participation has resulted in a research related injury, emotional or physical discomfort please contact: Dr. Sanjiv B. Amin, M.D at 585-273-2696

If you have any questions about your child's rights as a research subject, or any concerns or complaints, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315, Telephone (585) 276-0005. For long-distance, you may call toll-free, (877) 449-4441. You may also call these numbers if you cannot reach the research staff or wish to talk to someone else.

Signature/Dates

Parent Permission

I have read (or have had read to me) the contents of this permission form and have been encouraged to ask questions. I have received answers to my questions. I agree to allow my child to participate in this study. I have received (or will receive) a copy of this form for my records and future reference.

Please check one of the boxes below regarding blood storage:

☐ **Yes, I agree to allow my baby's leftover blood to be stored for future research.**

☐ **No, I do not want my baby's blood to be stored for future research.**

Research Subject (Child's Name): _____Print Name

Parent's Name: _____Print Name

Parent's Signature _____ Date _____

Person Obtaining Permission

I have read this form to the parent and/or the parent has read this form. I will provide the parent with a copy of this permission form. An explanation of the research was given and questions from the parent were solicited and answered to the parent's satisfaction. In my judgment, the parent has demonstrated comprehension of the information. I have given the parent adequate opportunity to read the permission form before signing.

_____ Print Name and Title

_____ Signature _____Date