EXPERIMENTAL SUBJECT'S BILL OF RIGHTS
Medical Research Studies

The rights below are the rights of every person who is asked to be in a medical research study. As an experimental subject, you have the following rights:

1) To be told what the study is trying to determine.
2) To be told what will happen to you and whether any of the procedures, drugs, or devices is different from what would be used in standard practice.
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to you for research purposes.
4) To be told if you can expect any benefit from participating and, if so, what the benefit might be.
5) To be told the other choices you have and how they may be better or worse than being in the study.
6) To be allowed to ask any questions concerning the study, both before agreeing to be involved and during the course of the study.
7) To be told what sort of medical treatment is available if any complications arise.
8) To refuse to participate or to change your mind about participating after the study is started. This decision will not affect your right to receive the care you would receive if you were not in the study.
9) To receive a copy of the signed and dated consent form.
10) To be free of pressure when considering whether you wish to agree to be in the study.

If you have other questions, please ask the researcher or research assistant. In addition, you may contact the Institutional Review Board, which is concerned with protecting volunteers in research projects. You may reach the IRB office by calling (916) 703-9151, from 8:00 a.m. to 5:00 p.m., Monday through Friday, or by writing to the Institutional Review Board, CTSC Bldg., Suite 1400, Rm. 1429, 2921 Stockton Blvd., Sacramento, California 95817.

______________________________ _______________________
Signature of Subject or Legal Representative — Date

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Protocol	APPROVED
225576	February 12, 2018

UNIVERSITY OF CALIFORNIA, DAVIS
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Investigator's Name: ARTHUR J. de Lorimier, MD
Department: PEDIATRICS, GASTROENTEROLOGY

STUDY TITLE: Use of an intravenous fish oil emulsion in infants with cholestasis

INTRODUCTION

Your baby needs TPN (total parenteral nutrition - the mixture of sugars, proteins and fats that is given into a vein) to help them grow.

Your baby's jaundice level (called the direct bilirubin) is high, and this makes us think that your baby's liver is being damaged. We have tried to help your baby's liver by making changes in the ingredients in your baby's TPN but this has not worked. This is a problem because if the liver continues to be damaged it can bleeding, infections and even death.

One possible treatment for this jaundice is a special type of fat (called OMEGAVEN) that we would use instead of the fat already in your baby's TPN (called INTRALIPID - this is the milky colored solution you may have seen going into your baby's iv line).). Omegaven is not licensed in the US so we would not normally be able to give it to your baby and we can not be completely sure how helpful this type of fat is, or whether it might lead to other problems for your baby.

WHY IS THIS STUDY BEING DONE?

The reason for this study is to see whether giving your baby Omegaven instead of intralipid into their vein as part of their TPN might help your baby's liver recover.

HOW MANY CHILDREN WILL TAKE PART IN THE STUDY?

Your baby will be one of twenty-five babies studied.

WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Your baby will be given Omegaven as part of their TPN instead of intralipid. Once we decide to give the Omegaven it can take several weeks for it be start because in needs to be delivered from Europe, and we may need to get approval from your insurance provider. The first dose of Omegaven must be given in the hospital, if you baby has already been discharged from the hospital when we decide to start Omegaven, he/she will need to be readmitted for about 24 hours so we can give the first dose in hospital.

We will continue to follow your baby's blood tests very closely, just as we would with any baby with serious liver disease, and any baby on TPN for a long time. Taking part in this study will not change which tests are measured, or how often.

The ONLY thing that should change as part of this study is what type of fat your baby receives as part of their TPN: Omegaven rather than intralipid.

If your baby does go home on Omegaven they will need to come back to the out-patient clinic at UC Davis every month where their growth will be checked and blood will be taken (2ml or just under ½ teaspoon) to assess your baby's blood count, blood clotting, serum chemistry, and bilirubin levels.

Babies must be monitored in hospital for their first dose of Omegaven. If you baby has gone home before getting Omegaven they will need to come back into the hospital overnight for their first dose. Before we do this we will need to make sure your insurance company/ other payor is willing to pay for this.

HOW LONG WILL MY CHILD BE IN THE STUDY?

Your baby will be in the study until their liver has recovered, or until they do not need to be TPN (i.e. do not need to be feed into their vein). If your baby no longer needs TPN we will have to stop Omegaven, whether or not your baby's liver has recovered.

If your baby goes home, or goes to another hospital, and their liver has not healed and the jaundice level is still high we will try and arrange for Omegaven to continue at home if your baby is still on TPN. This may not be possible, however, depending on who your doctor is and who pays for your medical bills.

CAN I STOP BEING IN THE STUDY?

Yes, you can stop being in the study at any time and for any reason. It will NOT affect anything about the rest of your baby's care.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?

When people started using Omegaven they were worried about high lipid levels, low platelets (cells that help the blood clot) and increased bleeding problems. These problems do not seem to be worse in babies getting Omegaven than in other babies with serious liver disease.

Omegaven does not include some fats that the body might need, but the current studies have not shown that to be a problem. But if we see signs that might be due to too little of these fats we will either try and test for that, or give some of those fats (in intralipid).

We are not sure, however, about the risk of Omegaven as only a few hundred children have received it. Because Omegaven is not licensed by the FDA it can be difficult to tell how safe Omegaven really is. There have been concerns that Omegaven might cause problems with bleeding or inadequate platelets (which help blood to clot), but these problems seem to be less common in babies that get Omegaven than those with cholestasis who stay on intralipid. If we find out more about the risk of Omegaven during the course of the study we will let you know.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

We hope Omegaven will help your baby's liver heal we do not know for sure whether this will happen.

WHAT OTHER CHOICES DO I HAVE IF MY CHILD DOES NOT TAKE PART IN THIS STUDY?

If you do not wish to take part in this study you do not have to. Your baby's care and treatment will not be affected by your decision (except that Omegaven will not be given).

WILL MY CHILD'S MEDICAL INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that your personal information will be kept confidential. However, we cannot

guarantee total privacy. Your personal information may be released if required by law. If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your medical records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law. Designated University officials, including the Institutional Review Board, the Food & Drug Administration have the authority to review research records. A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. At most, the Web site will include a summary of the results. You can search this Web site at any time. If information from the study is published or presented at scientific meetings, your name and other personal information will not be used.

WHAT HAPPENS IF MY CHILD IS INJURED BECAUSE SHE/HE TOOK PART IN THIS STUDY?

It is important that you promptly tell the Researcher if you believe that your child has been injured because of taking part in this study. If your child is injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. You do not lose any legal rights by signing this form.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Omegaven costs about $50-100 a day. The FDA allows us to bill your private or public insurance carrier for this. But it is possible that they will refuse to pay for Omegaven. If this happens, we will try and pay for Omegaven from our own funds, or from the UCDMC pharmacy funds, or from UCDMC NICU funds.

If your baby has already been discharged from the hospital, we will ask your insurance provider to pay for the costs of the Omegaven and the 24h hospital admission. We will not admit your baby to the hospital of start Omegaven until we know that your insurance provider is okay with this.

We expect that families will not have to pay for Omegaven. BUT if your private or public insurance carrier will not pay for Omegaven, and if neither UCDMC pharmacy, or the UCDMC NICU has funds to pay for Omegaven; we may need to ask you to pay. HOWEVER, if this happens, we will tell you about it and you will have the option to stop Omegaven and not have to pay any money.

WHAT ARE MY RIGHTS IF MY CHILD TAKES PART IN THIS STUDY?

If you decide to take part in this study, your rights are

1. To decide if your baby takes part in this study
2. To decide whether your baby continues to the end of this study
3. To decide when your baby stops being in this study
4. To be told about any new information we have about Omegaven in babies with liver disease that might affect whether you want your baby to be in the study

DOES THE RESEARCHER HAVE A FINANCIAL INTEREST IN THIS RESEARCH STUDY?

The Investigator does not have any personal or financial interest in this study.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have questions, please ask us. You can talk to the Investigator about any questions or concerns you have about this study at:

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Arthur J. de Lorimier MD at pager number 916 816 1931 (anytime, emergency)

These numbers are for pagers. After you hear the message type in your telephone number and press #. Dr. de Lorimier will get back to you as soon as possible.

For questions about your rights while taking part in this study call the IRB Administration at (916) 703-9151 or write to IRB Administration, CTSC Building, Suite 1400, Room 1429, 2921 Stockton Blvd., Sacramento, CA 95817. The IRB Administration will inform the Institutional Review Board which is a group of people who review the research to protect your rights. The IRB Administration has also developed a web site designed to make you familiar with your rights. The web site discusses your basic rights as a research participant, an explanation of the informed consent process, the basic requirement that written consent be in a language understandable to you, and suggested sample questions to ask the research investigator regarding your participation in the study. This web site can be accessed at: www.research.ucdavis.edu/IRBAdmin.

ARE THERE OTHER RESEARCH OPPORTUNITIES?

If you are interested in being contacted for future research, please provide your phone number and/or email. This is completely optional.

____ (initials) Yes, I am willing to be contacted for future research opportunities. My phone number and/or email: _____.

My signature below will indicate that I have decided to participate in this study as a research subject. I have read and understand the information above. I understand that I will be given a signed and dated copy of this consent form and the Bill of Rights.

_____ _____
Signature of Subject or Legal Representative Print Name

_____
Date

_____ _____
Signature of Person Obtaining Consent Print Name of Person Obtaining Consent

_____
Date

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