H-23365- COMPASSIONATE USE OF AN INTRAVENOUS FAT EMULSION COMPRISED OF FISH OIL IN THE TREATMENT OF PARENTERAL NUTRITION INDUCED LIVER INJURY IN CHILDREN

**Background**

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

Your child is unable to tolerate enough of his/her feedings orally to grow. He/She requires that nutrition be given by vein (called intravenous or IV parenteral nutrition (PN)). Although this IV nutrition is necessary and life sustaining, it can result in severe liver disease. Your child has developed this severe liver disease. We call this liver disease cholestasis. Experiments have shown that the IV fat mixture (called Intralipid®) your child recieves as a part of his/her IV nutrition may be contributing to this liver disease. A different fat mixture, called Omegaven® could be used in place of Intralipid® for your child. Omegaven® contains 10% fish oil, which is different from Intralipid® which contains soybean oils.

The major difference between Omegaven and Intralipid is that Omegaven contains mostly omega-3 fatty acids (in the form of fish oil) and Intralipid contains mostly omega-6 fatty acids (in the form of soybean oil).

To date, approximately 1,000 children around the world have been studied using Omegaven® including over 170 at Texas Children's Hospital. Babies who received the Omegaven® had a better outcome with fewer having long-term jaundice, needing a liver transplant, or dying than those who received the usual Intralipid®.

This research study involves use of a drug (the Omegaven®) that is not approved for use in the US. This means the drug has not yet been approved by the Food and Drug Administration (FDA). However, given your child's condition, we have received permission through the Federal Food and Drug Administration (FDA) to make this product available to your child. This treatment is considered investigational because it is still being researched and is not available in the US except through research studies such as this one. Information from this research will help determine whether the drug should be approved by the FDA in the future.

**Purpose**

We want to find out if this new intravenous fat mixture (Omegaven®) will help reduce the severity (or seriousness) of liver disease or help put an end to liver disease in infants.

**Procedures**

The research will be conducted at the following location(s):
Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion.

Omegaven® is a fat solution given through a vein together with solutions containing dextrose (sugar) and amino acids (protein). Because we believe other fat mixtures are contributing to your child's liver

disease, we would administer Omegaven® alone or in combination with the dextrose and amino acid solution (the Parenteral Nutrition or PN).

While inpatient, your child will receive the Omegaven® fat solution. The same standards of care provided to all patients receiving IV nutrition solutions will be followed. This IV solution may be given either through a peripheral or central catheter depending on your child's IV access, and is usually provided for 24 hours per day.

Your child will receive treatment for as long as s/he needs IV nutrition. If your child no longer needs IV nutrition (because he/she is able to tolerate feedings), the Omegaven® will be stopped as well.

We will review your child's medical record and record information important to our research, including measurements such as weight, length, and head circumference, length and type of feedings, lab results from routine blood work, and infections.

We will continue to perform blood tests regularly to monitor how your child is handling the new treatment. If your child has not received any feeding into his/her gut for more than 4 weeks, we will draw less than 1 tsp of blood to measure for any incidence of essential fatty acid deficiency. For every 4 weeks that your child does not have any feedings into his/her gut, we will draw less than 1 tsp of blood for the essential fatty acid deficiency measurement. These blood draws will be scheduled with other routine blood work that your child will need for his/her medical care. Although these results will not be readily available, we would not change your child's treatment unless clinical symptoms of a deficiency appear.

All records associated with you/your child's participation in this study will be confidential. However, because the Food and Drug Administration (FDA) regulates the use of this drug, agents of the FDA may have access to these records during the course of their duties. A third party (Fresenius-Kabi, the manufacturer of Omegaven and their data management company) may also review your/your child's medical record information that has been recorded for study purposes. All study information will be coded (given a study identification number instead of you/your child's name).

**Research related health information**

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology

findings, etc.

- Demographic information (name, D.O.B., age, gender, race, etc.)

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law.

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research

Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, Data and Safety Monitoring Board, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. Muralidhar Premkumar
6621 Fannin Street, Suite WT6104
Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

**Potential Risks and Discomforts**
So far, research has not revealed any complications from this intervention in any of the approximately 500 infants who have received Omegaven®. The manufacturer has indicated that there may be increased risk of an allergic reaction to this product in patients with egg or shellfish allergies. The manufacturer doesn't recommend use of Omegaven® in patients with severe bleeding problems.

The long term side effects of Omegaven® are unknown. Although there is a potential risk of a prolonged bleeding time and bleeding complications, this has not been seen in any of the infants who have

received Omegaven® anywhere in the United States. There is also a potential increased risk of non-liver complications such as infections. There is a possibility of developmental delay and we encourage you to follow up with appointments at the TCH Special Needs Clinic after your baby is discharged from the hospital. There may be other side effects of getting the Omegaven® that we do not know about yet.

Due to lack of experience, the manufacturer does not recommend the use of the Omegaven® in patients with severe liver or renal insufficiency (liver or kidney problems/disorders). Therefore, the risk associated with the use of this product in your child, given that she/he has severe liver injury is not known.

Omegaven® may be associated with essential fatty acid deficiency, although clinical signs have not been seen in infants and recent research has not shown this to be a serious problem. These "essential fatty acids" are the fatty acids that the body does not produce. If your infant does not receive any feedings into his/her gut at all for more than 4 weeks, then blood may be drawn to measure the essential fatty acid level; however these results will not be available to make decisions about your infant's treatment. The long term effects of essential fatty acid deficiency in infants are not known.

To date approximately 500 children around the world have been studied using Omegaven® including including over 100 in Boston and 59 at Texas Children's Hospital. Both the babies in Boston and those at Texas Children's have been shown to have a shorter length of time of having jaundice, and perhaps less of them went on to need a liver transplant compared to what has been reported at that center previously. However there has been no study comparing Omegaven® to Intralipid® directly. The long term risks related to the use of Omegaven® are unknown although no long-term complications have been reported anywhere in the United States.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

**Potential Benefits**
The benefits of participating in this study may be: that your child's liver may get better while he/she continues to grow. However, you may receive no benefit from participating.

**Alternatives**
You may choose to not participate in this study.

**Subject Costs and Payments**

You will be billed for the cost of the Omegaven® as part of your hospital bill. This is the only cost of this research study. The approximate cost of 1 month is approximately $1056.00.

You will not be paid for taking part in this study.

**Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, MURALIDHAR HEBBUR PREMKUMAR, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Dr. Murali Premkumar at 832-826-7980 during the day and Dr. Premkumar or the clinical neonatologist on call at 832-826-1380 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

| | |
|---|---|
| Subject | Date |
| Legally Authorized Representative<br>Parent or Guardian | Date |
| Investigator or Designee Obtaining Consent | Date |
| Witness (if applicable) | Date |
| Translator (if applicable) | Date |

**Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**

**Consent for HOME USE of Omegaven (including READMISSIONS to Texas Children's Hospital)**

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**Background**

You are invited to take part in a research study. Please read this information and feel free to ask any questions before you agree to take part in the study.

Your child is unable to tolerate enough of his/her feedings orally to grow. He/She requires that nutrition be given by vein (called intravenous or IV parenteral nutrition (PN)). Although this IV nutrition is necessary and life sustaining, it can result in severe liver disease. Your child has developed this severe liver disease. We call this liver disease cholestasis. Experiments have shown that the IV fat mixture (called Intralipid®) your child receives as a part of his/her IV nutrition may be contributing to this liver disease. A different fat mixture, called Omegaven® could be used in place of Intralipid® for your child. Omegaven® contains 10% fish oil, which is different from Intralipid® which contains soybean oils.

The major difference between Omegaven and Intralipid is that Omegaven contains mostly omega-3 fatty acids (in the form of fish oil) and Intralipid contains mostly omega-6 fatty acids (in the form of soybean oil).

To date approximately 1,000 children around the world have been studied using Omegaven® including over 170 at Texas Children's Hospital. Babies who received the Omegaven® had a better outcome with fewer having long-term jaundice, needing a liver transplant, or dying than those who received the usual Intralipid®.

Boston Children's Hospital has seen improvement in over 50 children who have received Omegaven® long-term (at home) and no negative effects have been seen. Use in this long-term fashion may delay or prevent the need to do an intestinal transplant related to ongoing liver failure.

This research study involves use of a drug (the Omegaven®) that is not approved for use in the US. This means the drug has not yet been approved by the Food and Drug Administration (FDA). However, given your child's condition, we have received permission through the Federal Food and Drug Administration (FDA) to make this product available to your child. This treatment is considered investigational because it is still being researched and is not available in the US except through research studies such as this one. Information from this research will help determine whether the drug should be approved by the FDA in the future.

**Purpose**

We want to find out if this new intravenous fat mixture (Omegaven®) will help reduce the severity (or seriousness) of liver disease or help put an end to liver disease in infants.

**Procedures**

The research will be conducted at the following location(s):
Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's

Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion.

Omegaven® is a fat solution given through a vein together with solutions containing dextrose (sugar) and amino acids (protein). Because we believe other fat mixtures are contributing to your child's liver disease, we would administer Omegaven® alone or in combination with the dextrose and amino acid solution (the Parenteral Nutrition or PN).

At home, your child will receive the Omegaven® fat solution. The same standards of care provided to all patients receiving IV nutrition solutions will be followed. This IV solution may be given either through a peripheral or central catheter depending on your child's IV access, and is usually provided for 24 hours per day.

Your child will receive treatment for as long as he/she needs IV nutrition. If your child no longer needs IV nutrition (because he/she is able to tolerate feedings), the Omegaven® will be stopped as well.

If your child did not get Omegaven® while inpatient at TCH or at another hospital, you must bring him/her to TCH for a hospital admission of 48 hours in order to begin the Omegaven treatment. During this time of observation, you will be educated about the home use of Omegaven. Routine lab work on your child will be done at this visit and the results will be recorded for study purposes. Results from this first study visit will determine for sure if your child can get the Omegaven®.

If your child got Omegaven® while inpatient at TCH or at another hospital, the no additional hospitalization will need to be done. You must bring your child to the TCH Pediatric Intestinal Rehabilitation Clinic for the first outpatient clinic visit in order to be in this study. Routine lab work on your child will be done at this visit and the results will be recorded for study purposes. Results from this first study visit will determine for sure if your child can get the Omegaven®.

After the initial visit at the TCH Pediatric Intestinal Rehabilitation Clinic and your child is approved to get the Omegaven®, your child's clinic doctor will make arrangements with a home health agency so that you can get it at home.

You and your child will return to the TCH Pediatric Intestinal Rehabilitation Clinic for routine follow-up visits. You and your child will return to the clinic every 2 weeks for the first 2 months of treatment. After that, you and your child will return to the clinic on a monthly basis, or as directed by the clinic team. Orders for home use of Omegaven® will be signed by the doctor at the clinic visits. These follow up visits are very important to monitor the health and safety of your child. If you do not return for your clinic visits, the study doctors may drop your child from the study, meaning that your child would not be able to get more Omegaven®.

Routine monitoring done at clinic appointments and at home will be recorded for study purposes. This can include your child's weight, height, head circumference, a new diagnosis, surgical procedures,

medications, readmissions to the hospital, infections, feeding plans, lab results, and other data that may be useful for our study.

Your child will have blood work done to monitor his/her health as part of the routine care that is done through the clinic. Lab monitoring will typically be done every week to two weeks at home and at each clinic visit. No blood work will be done for study purposes only.

Routine evaluations done through the home health service will continue as usual. You will be billed for the Omegaven® at home. Thus far, we are not aware of any Medicaid rejections of Omegaven® in our population and anticipate that Medicaid will continue to cover the cost for home use.

If your child receives Omegaven at home and is later readmitted to TCH, the Omegaven and monitoring will proceed the same way as for all patients getting it in the hospital. You do not need to sign a new consent form for your child to receive Omegaven during readmissions to TCH.

While inpatient, your child will receive the Omegaven® fat solution. The same standards of care provided to all patients receiving IV nutrition solutions will be followed. This IV solution may be given either through a peripheral or central catheter depending on your child's IV access, and is usually provided for 24 hours per day.

Your child will receive treatment for as long as s/he needs IV nutrition. If your child no longer needs IV nutrition (because he/she is able to tolerate feedings), the Omegaven® will be stopped as well.

We will review your child's medical record and record information important to our research, including measurements such as weight, length, and head circumference, length and type of feedings, lab results from routine blood work, and infections.

We will continue to perform blood tests regularly to monitor how your child is handling the new treatment. If your child has not received any feeding into his/her gut for more than 4 weeks, we will draw less than 1 tsp of blood to measure for any incidence of essential fatty acid deficiency. For every 4 weeks that your child does not have any feedings into his/her gut, we will draw less than 1 tsp of blood for the essential fatty acid deficiency measurement. These blood draws will be scheduled with other routine blood work that your child will need for his/her medical care. Although these results will not be readily available, we would not change your child's treatment unless clinical symptoms of a deficiency appear.

In the event of injury resulting from this research, Baylor College of Medicine and/or Coram Specialty Infusion Services are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community.

All records associated with you/your child’s participation in this study will be confidential. However, because the Food and Drug Administration (FDA) regulates the use of this drug, agents of the FDA

may have access to these records during the course of their duties. A third party (Fresenius-Kabi, the manufacturer of Omegaven and their data management company) may also review your/your child's medical record information that has been recorded for study purposes. All study information will be coded (given a study identification number instead of you/your child's name).

**Research related health information**

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

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The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion.

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Use or Disclosure Required by Law

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Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

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Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, Data and Safety Monitoring Board, CNRC: Children's Nutrition Research Center, TCH: Texas Children's Hospital, TCH: Texas Children's Hospital General Clinical Research Center, TCH: Texas Children's Hospital The Woodlands, and Texas Children's Hospital- Women's Pavilion may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Dr. Muralidhar Premkumar
6621 Fannin Street, Suite WT6104
Houston, TX 77030

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

**Potential Risks and Discomforts**
So far, research has not revealed any complications from this intervention in any of the approximately 500 infants who have received Omegaven®. The manufacturer has indicated that there may be increased risk of an allergic reaction to this product in patients with egg or shellfish allergies. The manufacturer doesn't recommend use of Omegaven® in patients with severe bleeding problems.

The long term side effects of Omegaven® are unknown. Although there is a potential risk of a prolonged bleeding time and bleeding complications, this has not been seen in any of the infants who have received Omegaven® anywhere in the United States. There is also a potential increased risk of non-liver complications such as infections. There is a possibility of developmental delay and we encourage you to follow up with appointments at the TCH Special Needs Clinic after your baby is discharged from the hospital. There may be other side effects of getting the Omegaven® that we do not know about yet.

Due to lack of experience, the manufacturer does not recommend the use of the Omegaven® in patients with severe liver or renal insufficiency (liver or kidney problems/disorders). Therefore, the risk associated with the use of this product in your child, given that she/he has severe liver injury is not known.

Omegaven® may be associated with essential fatty acid deficiency, although clinical signs have not been seen in infants and recent research has not shown this to be a serious problem. These "essential fatty acids" are the fatty acids that the body does not produce. If your infant does not receive any feedings into his/her gut at all for more than 4 weeks, then blood may be drawn to measure the essential fatty acid level; however these results will not be available to make decisions about your infant's treatment. The long term effects of essential fatty acid deficiency in infants are not known.

To date approximately 500 children around the world have been studied using Omegaven® including ® including over 100 in Boston and 59 at Texas Children's Hospital. Both the babies in Boston and those at Texas Children's have been shown to have a shorter length of time of having jaundice, and perhaps less of them went on to need a liver transplant compared to what has been reported at that center previously. However there has been no study comparing Omegaven® to Intralipid® directly. The long

term risks related to the use of Omegaven® are unknown although no long-term complications have been reported anywhere in the United States.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

**Potential Benefits**
The benefits of participating in this study may be: that your child's liver may get better while he/she continues to grow. However, you may receive no benefit from participating.

**Alternatives**
You may choose to not participate in this study.

**Investigator Withdrawal of Subject from a Study**

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you (for example, if you move to another city, if you do not take your study medication, or if you have a serious reaction to your study medication) or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

**Subject Costs and Payments**

You will be billed for the cost of the Omegaven® as part of your bill at Texas Children's Hospital. This is the only cost of this research study. The approximate cost of 1 month is approximately $1056.00.

You will not be paid for taking part in this study.

**Subject's Rights**
Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, MURALIDHAR HEBBUR PREMKUMAR, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: Dr. Murali Premkumar at 832-826-7980 during the day and Dr. Premkumar or the clinical neonatologist on call at 832-826-1380 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

**Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals**

**Consent for HOME USE of Omegaven (including READMISSIONS to Texas Children's Hospital)**

H-23365- COMPASSIONATE USE OF AN INTRAVENOUS FAT EMULSION COMPRISED OF FISH OIL IN THE TREATMENT OF PARENTERAL NUTRITION INDUCED LIVER INJURY IN CHILDREN

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

| | |
|---|---|
| Subject | Date |
| Legally Authorized Representative<br>Parent or Guardian | Date |
| Investigator or Designee Obtaining Consent | Date |
| Witness (if applicable) | Date |
| Translator (if applicable) | Date |