Appendix B: Supplement Diet Group

Project Title: **Neurodevelopmental Effects of Donor Human Milk vs. Preterm Formula in ELBW infants**

Research Team:

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.
If you have any questions about or do not understand something in this form, you should ask the research team for more information.
You should discuss your participation with anyone you choose such as family or friends.
Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you and your baby to participate in this research study because you have delivered a baby who weighed less than or equal to1000 g at birth. We are interested in studying two different diets for infants like yours, when mother's breastmilk is unavailable for feeding.

In cases where a mother is unable or chooses not to provide breastmilk for her premature baby, or is unable to produce enough for the baby's needs, there are two options: premature infant formula or donor breastmilk. Premature infant formula is widely used throughout the United States, and has been designed specifically for the special needs of premature babies. Donor breastmilk is a newer option that is increasing in use. Donor breastmilk is obtained from breastfeeding mothers who pump and donate their extra breastmilk. The breastmilk is Pasteurized (heat treated) to make it sterile and safe for use. Just like mother's own breastmilk, the neonatal team may add powder or liquid, called fortifier, to donor breastmilk to increase the calories in the breastmilk, and provide vitamins and minerals that premature babies need.

It is known that mother's own breastmilk has special benefits for premature babies, including lower risks of infection in the NICU and better scores on developmental tests at age 18-22 months, but it is not known if donor breastmilk has the same benefits.

The purpose of this research study is to compare premature infant formula and donor breastmilk in order to determine if donor breastmilk offers babies the same benefits as mother's breastmilk. We will randomly assign (like the flip of a coin) your baby to receive donor breastmilk or premature infant formula as their diet while in the NICU for any feedings for which your own breastmilk is not available. **Your baby will receive all the breastmilk you make,** but if additional milk is needed, the baby will receive either donor breastmilk or formula until transition to a home going diet your doctor will choose. We will then compare the numbers of infections and complications in the NICU, growth rates, and neurodevelopmental test scores at 22-26 months between the two groups, to see if there are differences.

Information about this study is available on a public registry website (http://clinicaltrials.gov/ Identifier: NCT 01534481).

HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 40 infants and their mothers will take part in this study at the University of Iowa.

Approximately 670 infants and their mothers will take part in this study conducted at 16 other sites around the country.

HOW LONG WILL I BE IN THIS STUDY?
If you agree for yourself and your baby to take part in this study, your involvement will last until your baby is 22-26 months old. You will provide information while your baby is in the NICU, and information will be gathered at a follow-up visits when he or she is 22-26 months old.

WHAT WILL HAPPEN DURING THIS STUDY?
If you agree to participate in the study, your baby will be randomly assigned, like the flip of a coin, to be fed either premature infant formula or donor breastmilk for all feedings for which your own breastmilk is not available and until transition to a home going diet your doctor will choose.

If you are breastfeeding but are unable to provide enough breastmilk for your baby, we will randomly assign your baby to formula or donor breastmilk for the remainder of their diet. They would receive all the breastmilk you produce, but when your supply is not sufficient will be randomly assigned to get either formula or donor breastmilk as the rest of their diet during their hospital stay and until transition to a home going diet your doctor will choose.

All other parts of your baby's care will be the standard treatments for premature babies in the NICU.

All babies in the study will have the following:
We will record the age of your baby when they received their first feeding, and the age at which they were receiving all milk/formula, and no longer needed IV nutrition.
We will record your baby's weight (using the scale routinely used), once a week until your baby goes home or is 120 days old. His or her length (using a special board to measure premature babies), and head circumference (using the paper measuring tape routinely used) will also be measured and recorded once every other week. We will also record once a week if your baby had any trouble with his or her feedings in the previous 24 hours, including if their feedings were stopped..

During your baby's hospital stay, we will collect information from his or her medical chart, including medications used, infections treated, lab results, and any diagnoses your baby may have, such as lung disease or eye problems.

All babies who participate in the study will return to the High Risk Infant Follow-up Clinic between the age of 22 and 26 months. At this follow-up visit, which will take approximately two hours, a medical exam and developmental testing will take place. Your baby will be weighed and have their length and head circumference measured.

The following chart is a summary of what will happen and when:

During Hospital Stay	After Discharge
	Follow-up visit at 22-26 mo
Randomized formula or donor breastmilk diet	Medical exam results: Your baby will have a general medical exam similar to a well-baby checkup.
Recording of measurements of weight (once a week). Measurement of length and head circumference (every other week).	Developmental testing: You will answer questions about what new milestones your baby has reached since the last visit, including things like sitting, crawling, holding toys, and talking. The nurse practitioner will also play with your baby to get them to demonstrate their motor and social skills.
Medical chart information collected: Medical diagnoses that your baby receives during hospitalization, medications he has been given, infections, feeding tolerance, will be recorded in the study records	Questionnaire about home and family
This phase ends when baby is discharged from the hospital or is 120 days old	This phase ends at the 22-26 month follow-up visit

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. The use of premature infant formula and donor breastmilk as the diet for premature infants is within the usual standard of care in the United States. Infant formulas have been recalled due to bacterial contamination, and we use the safest (liquid) formula products available to decrease this small risk. Pasteurized donor breastmilk carries a small risk of infection, similar to, but smaller than, that of blood transfusion. In the 25 years that donor breastmilk has been used in the United States, there have been no reported cases of infection caused by donor breastmilk.

Some of the interview questions may make you uncomfortable. You may choose not to answer any or all of the questions.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if your baby will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the knowledge learned may help in choosing the best diet for premature babies who are not able to receive all mother's breastmilk.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could choose for your baby to receive donor breastmilk or premature infant formula if you elect not to breastfeed or are unable to do so. (In centers that do not currently use donor milk, this sentence should be changed to: "Instead of being in this study, you could choose for your baby to receive premature infant formula if you elect not to breastfeed or are unable to do so. Donor breastmilk is currently not used in this NICU except in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance carrier will remain responsible for you and your baby's regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?
You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

WHO IS FUNDING THIS STUDY?
The National Institutes of Health (NIH), via the National Institute of Child Health and Development (NICHD), is funding this research study. This means that the University of Iowa is receiving payments from NIH, to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
No compensation for treatment of research-related illness or injury is available from the University of Iowa unless it is proven to be the direct result of negligence by a University employee.
If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?
We will keep you and your baby's participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your and your baby's participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you and your baby.

- ☐ federal government regulatory agencies,
- ☐ The U.S. Food and Drug Administration (FDA)
- ☐ auditing departments of the University of Iowa, and
- ☐ the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your and your baby's confidentiality, we will label information with a code number. The study logs linking the code number with your infant's identity will be kept in a locked office, in a locked file cabinet and on password-protected computer files. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you and your baby cannot be directly identified.

A copy of this Informed Consent Document will be placed in your and your baby's medical record.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?
The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health

information" about you and your baby for purposes of this research study. Protected health information is information that personally identifies you and your baby and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you and your baby, as described in this document, for purposes of this research study and for your baby's treatment. Once University of Iowa Health Care has disclosed you and your baby's protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your and your baby's confidentiality as described under "Confidentiality."

We may share your and your baby's health information related to this study with other parties including federal government regulatory agencies, the FDA, the University of Iowa Institutional Review Boards and support staff, and The National Institute of Health, National Institute of Child Health and Development.

You and your baby cannot participate in this study unless you permit us to use your and your baby's protected health information. If you choose *not* to allow us to use your and your baby's protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect you and your baby's right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you and your baby.

Although you may not be allowed to see study information until after this study is over, you may be given access to you and your baby's health care records by contacting you and your baby's health care provider. Your permission for us to access or create protected health information about you and your baby for purposes of this study has no expiration date. You may withdraw your permission for us to use your and your baby's health information for this research study by sending a written notice to:

Dr. Tarah Colaizy
University of Iowa Hospitals and Clinics
200 Hawkins Drive
Dept of Pediatrics, 8809 JPP
Iowa City, IA 52242

However, we may still use your and your baby's health information that was collected before withdrawing your permission. Also, if we have sent you and your baby's health information to a third party, such as the study sponsor, or we have removed you and your baby's identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose for you and your baby not to take part at all. If you choose for you and your baby to be in this study, you may stop and may stop his or her participation at any time. If you decide not to be in this study, or if you stop you or your child's participation at any time, you and your baby won't be penalized or lose any benefits for which you and your baby otherwise qualify.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue you or your baby's participation in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers [or the study sponsor] might decide to end you and your baby's participation in this research study earlier than planned. This might happen because your baby needs to be treated in a way outside the study protocol.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself or research-related injury, please contact: Dr. Tarah Colaizy at (319) 356-3508 or Karen Johnson, RN at (319) 356-2924.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 340 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (Mother) (printed): _____

Subject's Name (Infant) (printed): _____

Parent/Guardians Name and Relationship to Subject:

_____ _____
(Name - printed) (Relationship to Subject - printed)

Do not sign this form if today's date is on or after **EXPIRATION DATE: 11/08/11.**

_____ _____
(Signature of Parent/Guardian) (Date)
(Signature of Mother)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

Appendix A: Sample Consent for the Sole Diet Group

Project Title: **Neurodevelopmental Effects of Donor Human Milk vs. Preterm Formula in ELBW infants**

Research Team:

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.
If you have any questions about or do not understand something in this form, you should ask the research team for more information.
You should discuss your participation with anyone you choose such as family or friends.
Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you and your baby to participate in this research study because you have delivered a baby who weighed less than or equal 1000 g at birth. We are interested in studying two different diets for infants like yours, when mother's breastmilk is unavailable for feeding.

In cases where a mother is unable or chooses not to provide breastmilk for her premature baby, or is unable to produce enough for the baby's needs, there are two options: premature infant formula or donor breastmilk. Premature infant formula is widely used throughout the United States, and has been designed specifically for the special needs of premature babies. Donor breastmilk is a newer option that is increasing in use. Donor breastmilk is obtained from breastfeeding mothers who pump and donate their extra breastmilk. The breastmilk is Pasteurized (heat treated) to make it sterile and safe for use. Just like mother's own breastmilk, the neonatal team may add a powder or liquid, called fortifier, to donor breastmilk to increase the calories in the breastmilk, and provide vitamins and minerals that premature babies need.

It is known that mother's own breastmilk has special benefits for premature babies, including lower risks of infection in the NICU and better scores on developmental tests at age 18-22 months, but it is not known if donor breastmilk has the same benefits.

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Approximately 670 infants and their mothers will take part in this study conducted by investigators at 16 other sites around the country.

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If you agree for yourself and your baby to take part in this study, your involvement will last until your baby is 22-26 months old. You will provide information while your baby is in the NICU, and information will be gathered at a follow-up visits when he or she is 22-26 months old.

WHAT WILL HAPPEN DURING THIS STUDY?

If you agree to participate in the study, your baby will be randomly assigned, like the flip of a coin, to be fed either premature infant formula or donor breastmilk for all feedings during their hospital stay for which your breastmilk is not available and until transition to a home going diet your doctor will choose.

All other parts of your baby's care will be the standard treatments for premature babies in the NICU.

All babies in the study will have the following:

We will record the age of your baby when they received their first feeding, and the age at which they were receiving all milk/formula, and no longer needed IV nutrition.

We will record your baby's weight (using the scale routinely used), once a week until your baby goes home or is 120 days old. His or her length (using a special board to measure premature babies), and head circumference (using the paper measuring tape routinely used) will also be measured and recorded every other week. We will also record once a week if your baby had any trouble with his or her feedings in the previous 24 hours, including if their feedings were stopped,.

During your baby's hospital stay, we will collect information from his or her medical chart, including medications used, infections treated, lab results, and any diagnoses your baby may have, such as lung disease or eye problems.

All babies who participate in the study will return to the High Risk Infant Follow-up Clinic between the age of 22 and 26 months. At this follow-up visit, which will take approximately two hours, a medical exam and developmental testing will take place. Your baby will be weighed and have their length and head circumference measured.

The following chart is a summary of what will happen and when:

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	Follow-up visit at 22-26 mo
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Recording of measurements of weight (once a week). Measurement of length and head circumference (every other week).	Developmental testing: You will answer questions about what new milestones your baby has reached since the last visit, including things like sitting, crawling, holding toys, and talking. The nurse practitioner will also play with your baby to get them to demonstrate their motor and social skills.
Medical chart information collected: Medical diagnoses that your baby receives during hospitalization, medications he has been given, infections, feeding tolerance, will be recorded in the study records	Questionnaire about home and family
This phase ends when baby is discharged from the hospital or is 120 days old	This phase ends at the 22-26 month follow-up visit

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. The use of premature infant formula and donor breastmilk as the diet for premature infants is within the usual standard of care in the United States. Infant formulas have been recalled due to bacterial contamination, and we use the safest (liquid) formula products available to decrease this small risk. Pasteurized donor breastmilk carries a small risk of infection, similar to, but smaller than, that of blood transfusion. In the 25 years that donor breastmilk has been used in the United States, there have been no reported cases of infection caused by donor breastmilk.

Some of the interview questions may make you uncomfortable. You may choose not to answer any or all of the questions.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if your baby will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the knowledge learned may help in choosing the best diet for premature babies who are not able to receive all mother's breastmilk.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could choose for your baby to receive donor breastmilk or premature infant formula if you elect not to breastfeed or are unable to do so. (In centers that do not currently use donor milk, this sentence should be changed to: "Instead of being in this study,

you could choose for your baby to receive premature infant formula if you elect not to breastfeed or are unable to do so. Donor breastmilk is currently not used in this NICU except in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance carrier will remain responsible for you and your baby's regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?
You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

WHO IS FUNDING THIS STUDY?
The National Institutes of Health (NIH), via the National Institute of Child Health and Development (NICHD), is funding this research study. This means that the University of Iowa is receiving payments from NIH, to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIH for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
No compensation for treatment of research-related illness or injury is available from the University of Iowa unless it is proven to be the direct result of negligence by a University employee.
If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?
We will keep you and your baby's participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your and your baby's participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you and your baby.

- ☐ federal government regulatory agencies,
- ☐ The U.S. Food and Drug Administration (FDA)
- ☐ auditing departments of the University of Iowa, and
- ☐ the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your and your baby's confidentiality, we will label information with a code number. The study logs linking the code number with your infant's identity will be kept in a locked office, in a locked file cabinet and on password-protected computer files. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you and your baby cannot be directly identified.

A copy of this Informed Consent Document will be placed in your and your baby's medical record.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you and your baby for purposes of this research study. Protected health information is information that personally identifies you and your baby and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you and your baby, as described in this document, for purposes of this research study and for your baby's treatment. Once University of Iowa Health Care has disclosed you and your baby's protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your and your baby's confidentiality as described under "Confidentiality."

We may share your and your baby's health information related to this study with other parties including federal government regulatory agencies, the FDA, the University of Iowa Institutional Review Boards and support staff, and The National Institute of Health, National Institute of Child Health and Development.

You and your baby cannot participate in this study unless you permit us to use your and your baby's protected health information. If you choose *not* to allow us to use your and your baby's protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect you and your baby's right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you and your baby.

Although you may not be allowed to see study information until after this study is over, you may be given access to you and your baby's health care records by contacting you and your baby's health care provider. Your permission for us to access or create protected health information about you and your baby for purposes of this study has no expiration date. You may withdraw your permission for us to use your and your baby's health information for this research study by sending a written notice to :

Dr. Tarah Colaizy
University of Iowa Hospitals and Clinics
200 Hawkins Drive
Dept of Pediatrics, 8809 JPP
Iowa City, IA 52242

However, we may still use your and your baby's health information that was collected before withdrawing your permission. Also, if we have sent you and your baby's health information to a third party, such as the study sponsor, or we have removed you and your baby's identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose for you and your baby not to take part at all. If you choose for you and your baby to be in this study, you may stop and may stop his or her participation at any time. If you decide not to be in this study, or if you stop you or your child's participation at any time, you and your baby won't be penalized or lose any benefits for which you and your baby otherwise qualify.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue you or your baby's participation in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?
Under certain circumstances, the researchers [or the study sponsor] might decide to end you and your baby's participation in this research study earlier than planned. This might happen because your baby needs to be treated in a way outside the study protocol.

WHAT IF I HAVE QUESTIONS?
We encourage you to ask questions. If you have any questions about the research study itself or research-related injury, please contact: Dr. Tarah Colaizy at (319) 356-3508 or Karen Johnson, RN at (319) 356-2924.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 340 College of Medicine Administration Building, The University of Iowa, Iowa City, Iowa, 52242, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://research.uiowa.edu/hso. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (Mother) (printed): _____

Subject's Name (Infant) (printed): _____

Parent/Guardians Name and Relationship to Subject:

_____ _____
(Name - printed) (Relationship to Subject - printed)

Do not sign this form if today's date is on or after EXPIRATION DATE: 11/08/11.

_____ _____
(Signature of Parent/Guardian) (Date)
(Signature of Mother)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)