Attachment B—Consent to Participate in a Research Study

The Children's Hospital *of* Philadelphia®

Consent to Participate in a Research Study

Study Title: Developing Best Practices to Encourage Non-Residential Father's Participation in the National Children's Study: Perspectives from both unwed, Non-residential Mothers and Fathers.

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Study Sponsor: NIH/NICHD

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form that you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

Why are you being asked to take part in this study?

You are being invited to take part in this research study because your thoughts and feelings may help us understand the best way to approach people like you for participation in a future research study near where you live. This future study is called The National Children's Study and is scheduled to begin in your area in July 2010.

What is the purpose of this research study?

The purpose of this research study is to gain an understanding of the thoughts, feelings and attitudes that we should consider when trying to recruit and retain participants into The National Children's Study.

How many people will take part?

If you decide to be in this study, you will be one of about 64 people in this research study. You will participate in one of eight focus groups. Each focus group will have about 6-8 participants.

What is involved in the study?

The National Children's Study will gather information about how the chemical, physical, social, and family environments might influence the health and development of children in the United States. To better prepare to approach study participants in the future, we need to understand any issues and considerations that may be special to the area in which you live.

The purpose of this focus group study is to better understand how we can conduct the National Children's Study research project while considering the feelings and thoughts of people like you.

If you agree to take part in this study, your participation will last for about 1 ½ hours. The study involves participating in one focus group session. You may also be asked to participate in a phone interview after the focus group in order to clarify things that were said during the focus group session. This phone call may last up to 30 minutes.

Study Procedures

If you take part in this study you will be asked to participate in one focus group session lasting about 1 ½ hours. There will be a focus group moderator and several note takers in addition to the focus group participants. There will be about 6-8 study participants in each focus group. We will explain the goals of the National Children's Study and ask your opinion about the best way to conduct this study in your community and among people like you that live in your community. Each focus group will be audio taped.

You may also be asked to allow us to telephone you in order to clear up any questions that we may have after the group session has ended. This phone call may last up to 30 minutes.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. You may experience emotional stress during the focus group if a subject that is sensitive to you is discussed. You may refuse to answer questions at any time (even if you consent to take part in the study) and you may refuse to take part in the study at any time. We do not anticipate any other risks or discomfort to you from being in the study.

Even though we will stress to all participants that comments made during the focus group session should be kept confidential, it is possible that other participants may repeat comments outside of the group at some time in the future. Therefore, we encourage you to be as honest and open as you can, but remain aware of our limits in protecting confidentiality.

Are there any benefits to taking part in this study?

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may help us to determine the best way to approach participants for the National Children's Study in your area in the future.

Do you need to give your consent in order to participate?

Once you read this form and had your questions answered, you will be asked to decide if you wish to participate. If you wish to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. If you decide not take part or if you change your mind there will be no penalties or loss of any benefits to which you are otherwise entitled.

What about privacy and confidentiality?

Every effort will be taken to protect your identity as a participant in this study. There will be a special number given to each participant and this number will appear on all study papers. A list with your name and this special number will be kept separately from all other study papers, in a locked file cabinet with very limited access. The notes taken during the focus group sessions will contain only this study number.

The focus group session discussions will be audio taped. Both the tapes and the session notes will contain only this special number as an identifier. The tapes will be transcribed by a professional and all study materials will be stored in locked file cabinets. We will store these materials for no more than 5 years. After 5 years, the tapes will be destroyed and the list of names and numbers will also be destroyed.

The results of this study may be shown at meetings or published in journals to inform other doctors and health professionals. You will not be identified in any report or publication of this study or its results.

What are my rights and responsibilities as a research subject?

Taking part in a research study involves time and responsibilities. You must also agree not to reveal anything that you learn from group discussions or other activities.

Financial Information

Will you be paid for taking part in this study?

You will receive $40 for participating in this research. You will receive this at the end of the focus group session.

Who is funding this research study?

The National Institutes of Health (NIH) is providing funding for this study.

What if you have questions about the study?

If you have questions about the study, call the study doctors, Dr. Culhane at 267-426-6844 or Dr. Milbourne at 302-831-3633.

Consent to Take Part in this Research Study

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent Date:

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study and you are legally authorized to consent to your child's participation. ***NOTE:*** A foster parent is not legally authorized to consent for a foster child's participation.

Name of Subject	
Signature of Subject (18 years or older)	Date
Signature of Authorized Representative	Date
Name of Authorized Representative (if different than subject)	Relation to subject: ☐ Parent ☐ Legal Guardian