[STUDY CENTER]
[COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH]

CONSENT TO PARTICIPATE IN A RESEARCH PROJECT

Title: Assessing National Children's Study Recruitment Materials

Principal Investigator: [PROJECT PRINCIPAL INVESTIGATOR]

Sponsor: National Children's Study

Research Subject's Name:_____ Date:_____ _____

INVITATION TO TAKE PART AND INTRODUCTION

You are invited to volunteer for a research study. You are asked to take part because you are an [TARGET POPULATION] living in [PRIMARY SAMPLING UNIT] County. We will be adding the information we find out from volunteers in [PRIMARY SAMPLING UNIT] County, to the information we collect in other places across the United States. You will be asked to view materials and videos and discuss your reaction to these materials.

PURPOSE OF RESEARCH

The goal of this study is to collect individuals' feedback on materials, procedures, and strategies used to encourage people to participate in the National Children's Study.

YOUR RIGHTS

It is important for you to know that:

Your participation is entirely voluntary.

You may decide not to take part or decide to quit the study at any time, without any changes in the quality of the health care you receive.

You will be told about any new information or changes in the study that might affect your willingness to participate.

PROCEDURES

1. The moderator will collect information about you prior to the meeting, including race and ethnicity, age, zip code, and a few other items regarding family status. This information will not include your name or any other identification.

2. You will be asked to review a series of items providing information about the National Children's Study.

3. Once you have viewed the materials, you will participate in a group discussion so that you may provide more information about how effective you think these materials, procedures, and strategies might be. The group meeting will be recorded.

4. There will be about 8 to 10 people in the group. It will take about 30 minutes to review the items and another 30 minutes to participate in the follow up sessions with the moderator.

CONFLICT OF INTEREST DISCLOSURE
None

RISKS
We do not expect you to be harmed in any way as a result of helping in this research. However, if you are uncomfortable answering a question, you can skip that question. You can stop participating at any time.

BENEFITS
There are no direct benefits to you as a result of helping in this research. However, information you share in this study will be useful in developing effective procedures to recruit people to join the National Children's Study.

REASONS YOU MIGHT BE WITHDRAWN FROM THE STUDY WITHOUT YOUR CONSENT
You may be taken out of the research study if the investigator decides that continuing in the study would be harmful to you.

COSTS
There will be no additional cost to you from being in this research study.

COMPENSATION
You will be paid $25 to reimburse you for your time and travel.

CONFIDENTIALITY
Your privacy is important to us. Your research records will be confidential to the extent possible. In all records, you will be identified by a code number and your name will be known only to the researchers. Your name will not be used in any reports or publications of this study. However, the study sponsor (*National Children's Study)* and/or their representatives and the [STUDY CENTER] Institutional Review Board and/or their representatives may inspect your records that pertain to this research study. We will not allow them to copy down any parts of your identifiable information (e.g. your name) or take any of your identifiable information from our offices.

YOUR PARTICIPATION IN THIS PROJECT IS ENTIRELY VOLUNTARY. YOU MAY WITHDRAW FROM THE STUDY AT ANY TIME.

THE QUALITY OF CARE YOU RECEIVE AT THIS [LOCATION] WILL NOT BE AFFECTED IN ANY WAY IF YOU DECIDE NOT TO PARTICIPATE OR IF YOU WITHDRAW FROM THE STUDY.

QUESTIONS

Before you sign this consent form, please feel free to ask any questions you may have about the study or about your rights as a research subject. If other questions occur to you later, you may ask [PROJECT PRINCIPAL INVESTIGATOR] [CONTACT TELEPHONE NUMBER], the Principal Investigator. You may take as much time as you need to think this over. If at any time during or after the study, you would like to discuss the study or your research rights with someone who is not associated with the research study, you may contact the [LOCAL IRB CONTACT FOR STUDY CENTER]. The telephone number is [LOCAL IRB CONTACT NUMBER FOR STUDY CENTER].

CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT

Title: National Children's Study Recruitment and Retention Formative Research Project Focus Group

Principal Investigator: [PROJECT PRINCIPAL INVESTIGATOR]

Subject's Name:_____

I understand the purpose and procedures of this research project and the predictable discomfort, risks, and benefits that might result. I have been told that unforeseen events may occur. I have had an opportunity to discuss the risks and benefits of this research with the investigator and all of my questions have been answered. I agree to participate as a volunteer in this research project. I understand that I may end my participation at any time. I have been given a copy of this consent form.

_____ Date:_____
Subject's signature

STATEMENT OF PERSON OBTAINING CONSENT

I, the undersigned, have fully explained the details of this clinical study as described in the consent form to the subject named above.

_____ Date: _____
Signature of person obtaining consent

INVESTIGATOR'S DECLARATION

As the principal investigator or co-investigator on this study, I attest to the following:

- the nature and purpose of the study and study procedures, as well as the foreseeable risks, discomforts and benefits have been explained to the above-named subject
- this subject has been given the opportunity to ask questions and to have those questions answered by knowledgeable research staff
- this subject meets the inclusion/exclusion criteria for this study

I have considered and rejected alternative procedures for answering this research question.

_____ _____
PI Signature Date