## Vanderbilt University Institutional Review Board Informed Consent Document for Research

Principal Investigator: XXXXXXXXXXX Study Title: XXXXXXXXXXX Institution/Hospital: Vanderbilt University Revision Date: XXXXXX

This informed consent document applies to adults participating in the interviews or focus groups

Name of participant:

\_ Age: \_\_\_\_

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You are free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

# 1. Purpose of the study:

You are being asked to be in a research study because you drive a 4 to 8 year old child in your car and we would like to talk with you. We want to know what you think about using booster seats in cars and how you think we could get others to use booster seats for children.

# 2. Procedures to be followed and approximate duration of the study:

We are asking you to spend about 1-hour with us to answer some questions about booster seats either alone, or in a small group of 8 to 10 people. The process will be recorded and taped. The recording and tapes will be changed into written form by a person not in involved with the study. The written documents will not contain any information that will identify you. Everyone involved in the study will be symbolized by a code, created by themes like sex, age and race (example: black female 22).

# 3. Expected costs:

There is no cost to you for being in this research study.

## 4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

The time you spend with us may be inconvenient to your schedule.

# 5. Anticipated benefits from this study:

a) The things we find out from this research study will be used to talk to others about booster seat use for children in cars.

b) You may learn more about the right way to buckle up your child and you may be able to help others in your community by helping us.

Date of IRB Approval: XXXXXX 1

Date of IRB expiration: XXXXXX

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#### 6. Alternative treatments available:

You do not have to be in this research study, if you don't want to.

#### 7. Compensation for participation:

If you choose to be in this research study, you will be given a \$50 gift certificate to make up for the 1-hour of time you spend with us.

# 8. Circumstances under which the Principal Investigator may withdraw you from study participation:

If you express discomfort about being in this research study or if you act inappropriate (ie. swearing, aggressive behavior such as fighting) with the study staff or other volunteers, the Principal Investigator may withdraw you from the research study.

#### 9. What happens if you choose to withdraw from study participation:

Any information you provided prior to your decision to withdraw will be destroyed and will not be used as part of the analysis.

**10. Contact Information.** If you should have any questions about this research study or possibly injury, please feel free to contact XXXXXXXXX at XXX-XXXX.

For additional information about giving consent or your rights as a participant in this study, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

#### **11. Confidentiality Information:**

Other participants in your focus group will know how you answer questions. While we will discourage anyone from sharing this information outside of the group, we cannot guarantee **confidentiality by other focus group members.** We will do our best to keep all of your personal information private and confidential but absolute confidentiality cannot be guaranteed. Your information may be shared with institutional and/or governmental authorities, such as the Vanderbilt University Institutional Review Board, TN Dept of Transportation, or the Robert Wood Johnson Foundation; if you or someone else is in danger or if we are required to do so by law.

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## STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of volunteer
Consent obtained by:	
Date	Signature