

APPENDIX D

FDA Device Labeling Study Consent for Participation in Focus Group DRAFT 10.25.10

Introduction and Purpose:

You have been asked to be in a focus group as part of this study. The purpose of the group is to hear your thoughts about medical device labeling. RTI International, a non-profit company in North Carolina is conducting the group. The group is sponsored by the Food and Drug Administration (FDA).

Procedures:

A focus group is when about 6-10 people get together to talk about a topic and share their opinions. During the group, we will ask you to tell us your thoughts about medical device labeling. The group will take about 90 minutes.

We will be doing nine groups with a total of about 80 health care practitioners.

A moderator will be there to guide the talk. Some of the people working on the project may observe the discussion and take notes through a one-way mirror.

Risk/Discomforts:

There is no known physical risk to you from being in this study. You can decline to talk about any topic for any reason. You can also stop being in the group at any time.

Benefits:

There is no direct benefit to you for being in this interview. What we learn from the group will help FDA to revise and standardize medical device labeling.

Confidentiality:

We will be audio and video recording the group discussion. The audio and video files will be destroyed at the end of the project. Notes will be made of the recordings. We will only refer to first names in the notes. Your comments will be kept private to the extent allowable by law. The notes will be kept on a password-protected computer. Only authorized project staff will be able to see them. Any forms related to the project that have your name or information that could identify you will be kept in a locked file cabinet. These forms will be destroyed once the project ends. However, there is still a small risk that your privacy could be broken.

Payment:

We will give you \$250.00 (for prescribing health care professionals, \$150.00 for registered nurses, and \$100 for medical technical specialists) for your time, effort

Right to Refuse or Withdraw:

It is your choice to be in this group. You can choose not to talk about any topic. You can stop being in the group at any time.

Persons to Contact:

If you have questions about the group, you can call Dr. Michael Burke at (202) 728-2080. He can be reached between 9 AM and 5 PM Eastern Standard Time Monday - Friday. If you have questions about your rights as a participant, you can call RTI's Office of Research Protection toll-free at 1-866-214-2043.

Your Consent:

I have read this consent form. I had a chance to ask questions and my questions were answered. I was given a copy of this consent form.

Do you consent to participate in the group now?

Yes

No

Interviewer Signature

Date