

## APPENDIX A

### FDA Device Labeling Study Screening Script for Recruitment of Healthcare Practitioners DRAFT 10.25.10

[Name of recruiter] is recruiting healthcare providers from 3 specialty areas for a series of focus group discussions about medical devices. [Name of recruiter] is conducting the study on behalf of RTI International (RTI), who is currently working with the U.S. Food and Drug Administration (the FDA) to gather feedback and recommendations to inform FDA's approach to standardized practitioner labeling for 3 classes of medical devices and FDA's approach to regulation of these labels.

Practitioners will be asked to come to [location] on [TBD] to participate in a 90 minute focus group discussion. The focus group will be audio- and video-taped. The recordings will not be linked to your name and will be destroyed once a summary report is written. Each participant will receive an honorarium of [ ] in appreciation for his or her time.

**If you are interested in participating in this study, I'd like to ask you a few questions to determine if you qualify. Would you like to continue?**

#### NOTE TO RECRUITER: PLEASE TRY FOR A 50-50 MIX OF GENDER

1. Have you participated in a paid focus group or survey **within the past 6 months**?
  - No [CONTINUE]
  - Yes [THANK AND END]
  
2. **In the last 10 years**, have you or a family member worked for or been paid as a consultant for any of the following. This does not include participating in clinical studies:
  - Food and Drug Administration (FDA) [THANK AND END]
  - National Institutes of Health (NIH) [THANK AND END]
  - Centers for Disease Control and Prevention (CDC) [THANK AND END]
  - Other Federal agency [THANK AND END]
  - Medical device distributor or [THANK AND END]
  - Medical device manufacturer [THANK AND END]
  
3. What is your practice specialty? Choose one answer only.
  - Respiratory [CONTINUE – SEE GUIDELINES ON MIX]
  - Anesthesia [CONTINUE – SEE GUIDELINES ON MIX]
  - Infusion therapy [CONTINUE – SEE GUIDELINES ON MIX]
  - Wound care [CONTINUE – SEE GUIDELINES ON MIX]
  - Other (Please specify \_\_\_\_\_) [CONTINUE]

**Participants who choose any of the medical practice specialties listed qualify. If a participant selects "Other", please contact RTI to confirm a practitioner's eligibility.**

4. What type of practitioner are you? Choose one answer only.
  - Physician [CONTINUE – SEE GUIDELINES ON MIX]
  - Nurse (RNs only) [CONTINUE – SEE GUIDELINES ON MIX]

- Nurse Practitioner [CONTINUE – SEE GUIDELINES ON MIX]
- Physician Assistant [CONTINUE – SEE GUIDELINES ON MIX]
- Respiratory Therapist [CONTINUE – SEE GUIDELINES ON MIX]
- Respiratory Technician [CONTINUE – SEE GUIDELINES ON MIX]
- Nephrology Technician [CONTINUE – SEE GUIDELINES ON MIX]
- Nurse Wound Care Specialist [CONTINUE – SEE GUIDELINES ON MIX]
- Other (Please specify \_\_\_\_\_) [CONTINUE]

**Participants who choose any of the practitioner types listed qualify. If a participant selects “Other”, please contact RTI to confirm a practitioner’s eligibility.**

5. What type of setting do you work in most often?

- Private solo or group practice [CONTINUE – SEE GUIDELINES ON MIX]
- Public Health Clinic [CONTINUE – SEE GUIDELINES ON MIX]
- Outpatient Clinic [CONTINUE – SEE GUIDELINES ON MIX]
- Hospital [CONTINUE – SEE GUIDELINES ON MIX]
- Rehabilitation, nursing home, or hospice [CONTINUE – SEE GUIDELINES ON MIX]
- Home health [CONTINUE – SEE GUIDELINES ON MIX]
- Other (Please specify \_\_\_\_\_) [CONTINUE]

**Participants who choose any of the setting types listed qualify. If a participant selects “Other”, please contact RTI to confirm a practitioner’s eligibility.**

6. How many years have you been in clinical practice (post-residency)? [NOTE: for physicians] or post-licensure [NOTE: for all other segments]?

\_\_\_\_\_ years

**To qualify, the practitioner must have been in practice at least 3 years but no longer than 25 years.**

Closing for Ineligible Participants:

Thank you for answering all of my questions. Unfortunately, you are not eligible to be in this study. There are many possible reasons why people may not be eligible for the study. These reasons were decided earlier by the researchers. We value your interest in this research study and thank you for being willing to help us.

**Invitation:**

As I mentioned, we will be talking to healthcare practitioners about their views on medical device labeling and instructions for use. We would like to invite you to take part in a group discussion with 6-10 other practitioners like yourself.

We ask that you allot about 2 hours; your participation in the focus group discussion will last about 90 minutes. You will not be asked to buy anything. You will be asked your first name only, but can choose to use a made-up name if you prefer. You will be contacted a day or two before the discussion as a reminder. Everything you tell us will be kept confidential. We will not share your information with anyone outside the study, and your name will not appear in any report.

We're simply interested in your opinions. But if you begin to feel uncomfortable at any time, you can refuse to answer questions or leave the discussion. Your participation in this study poses no physical risks to you.

If you have questions about your rights as a participant, call the RTI project director at XXX-XXX-XXXX. Leave a message with your name and phone number, and someone will call you back as soon as possible.

For participating in the group, you will be paid for your time and effort and to help repay you for your travel expenses. Will you be able to join us?

Yes [CHECK SEGMENT AND SCHEDULE]

No [THANK AND END]

**If qualified and interested:** Record person's name, contact information (i.e., phone number and/or e-mail address), and time/date of focus group.

Name:

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Phone and E-Mail:

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Comments:

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Focus Group Date/Time:

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**PLEASE CONTACT RTI IF YOU HAVE QUESTIONS ABOUT A PRACTITIONER'S ELIGIBILITY!**