



### FDA Medical Device Labeling Telephone Script

1. Hello, my name is [INTERVIEWER NAME]. I am a representative for a not-for-profit research organization called RTI, and I am calling on behalf of the Food and Drug Administration, or the FDA. May I please speak with [NAME OF MEDICAL PROFESSIONAL]?

YES.....1→ **SKIP TO Q3**

NO- LEAVE MSSG WITH GATEKEEPER→**GO TO 2a**

NO- LEAVE VOICEMAIL.....3→**SKIP TO DIAL2D ON 1<sup>ST</sup>, 4<sup>TH</sup>, AND 7<sup>TH</sup> CALL ATTEMPT. ON 2<sup>ND</sup>, 3<sup>RD</sup>, 5<sup>TH</sup>, AND 6<sup>TH</sup> CALL ATTEMPT, RETURN TO CATI-CMS TO RECORD IN ROC.**

NO -HANG UP DURING INTRO (HUDI).....4→ **RECORD IN ROC AS REFUSAL NOT AVAILABLE, NO MESSAGE LEFT.....5→ RECORD IN ROC**

2a. I am calling from a research organization called RTI. We wanted to follow up with [NAME] regarding a letter we sent about participating in a survey about medical device labeling. We are conducting an important project, funded by the Food and Drug Administration (FDA), to examine what types of information need to be provided with medical devices, and how that information should be organized in device labeling.

We would appreciate [NAME]'s participation in the survey. It would only take about 30 minutes and [NAME] will receive [FILL INCENTIVE: \$75 FOR DOCTORS/PRESCRIBERS (GROUP 1); \$40 FOR NURSES (GROUP 2); \$25 FOR THERAPISTS/TECHNICIANS (GROUP 3)] as thanks for their time. [NAME] can complete the survey online at a time convenient for him/her. Please have [NAME] contact us at [CALL CENTER 800#] for information about how to complete the survey. Thank you!

RETURN TO CMS; CODE AS 212 – LEFT MSSG WITH GATEKEEPER.

**DIAL2D.** My name is [INTERVIEWER NAME], and I am calling from a research organization called RTI. We wanted to follow up with you regarding a letter we sent about participating in a survey about medical device labeling. We are conducting an important project, funded by the Food and Drug Administration (FDA), to examine what types of information need to be provided with medical devices, and how that information should be organized in device labeling. We would appreciate your participation in the survey. It would only take about 30 minutes for which you will receive [FILL INCENTIVE: \$75 FOR DOCTORS/PRESCRIBERS (GROUP 1); \$40 FOR NURSES (GROUP 2); \$25 FOR THERAPISTS/TECHNICIANS (GROUP 3)] as thanks for your time. You would complete the survey online at a time convenient for you. Please contact us at [CALL CENTER 800#] for information about how to complete the survey. Thank you!

- 1 LEFT MSSG ON MACHINE
- 2 PERSON PICKED UP (GO TO 1.)



3. [IF NEW PERSON ON THE PHONE: Hello, my name is [INTERVIEWER NAME]. I am a representative for a research organization called RTI]. I am calling to follow up on a letter we sent to you about participating in a survey about medical device labeling. The letter explained that we are conducting an important project, funded by the Food and Drug Administration (FDA), to examine what types of information need to be provided with medical devices, and how that information should be organized. Do you recall receiving this letter?

YES.....1 → **SKIP TO Q4**

NO.....2

DK.....3

3a. Let me share some information about the study with you. The purpose of this project is to examine what information needs to be provided with medical devices, and how that information should be organized. We are asking health care professionals to provide their opinion about an example medical device label created for this survey. The project findings will provide evidence to inform the FDA’s regulatory approach to standardizing device labeling.

We would like you to participate in the project because the FDA really wants to hear what medical professionals want related to device labeling. I can email you information so you can participate online. To thank you for your time, you will be paid [FILL INCENTIVE: \$75 FOR DOCTORS/PRESCRIBERS (GROUP 1); \$40 FOR NURSES (GROUP 2); \$25 FOR THERAPISTS/TECHNICIANS (GROUP 3)].

Would you be interested in participating?

YES .....1 → **SKIP TO Q6/GET\_EMAIL**

DON’T WANT TO PARTICIPATE.....2 → **SKIP TO Q10**

4. Ok, thank you. I’m calling to follow-up on that letter. We would like you to participate in the survey because the FDA really wants to hear what medical professionals want related to device labeling.

[PRESS 1 TO CONTINUE.]

4a. Do you still have the letter from us with the survey web address, and your log on information?

[IF R IS NOT SURE IF THEY STILL HAVE THE LETTER, CODE AS “DK.”]

YES.....1 → **SKIP TO Q9**

NO.....2

DK.....3



- 5. [FILL “Since you are not sure...” only if 4a=DK. [Since you are not sure if you still have the letter, I would like to see if I can email you this information./In order to participate in the project, I will need to email you this information.] The survey itself will take no more than 30 minutes to complete. To thank you for your time, you will be paid [FILL INCENTIVE: \$75 FOR DOCTORS/PRESCRIBERS (GROUP 1); \$40 FOR NURSES (GROUP 2); \$25 FOR THERAPISTS/TECHNICIANS (GROUP 3)].

Would you be interested in participating?

YES.....1

DON'T WANT TO PARTICIPATE.....2 → **SKIP TO Q10**

- 6. [GET\_EMAIL] Ok, thanks. I would like to collect your e-mail address so I can send you the information to access the online survey. The email will include a link to our online survey, your username, and your password. We will **only** use your email address to send you the information you need to participate in this study for the FDA.

RECORD E-MAIL ADDRESS: \_\_\_\_\_@\_\_\_\_\_

[INTERVIEWER: READ EMAIL ADDRESS BACK TO RESPONDENT TO CONFIRM.]

- 7. And to confirm I am speaking with the correct person, may I please have your full name?

RECORD DOCTOR'S NAME: \_\_\_\_\_

- 8. Thank you. You can expect to receive an e-mail with information to access the online survey within the next few days. This email will be sent from the “FDA Device Label Survey.” The survey will take approximately 30 minutes to complete. Once you have completed the survey we will send a check to thank you for participating. I also want you to know that your participation in this research will be kept private to the fullest extent allowed by law.

8b. Your participation in this research is also voluntary. Refusal to participate will involve no penalty, and you may discontinue participation at any time. There are no direct benefits to you for completing the survey, however, the data will be used to develop guidance for device labeling that may lead to an increase in the safe and effective use of medical devices, and a reduction in adverse events associated with the use of medical devices. If you have any questions about the study, please feel free to call us at 1-800-334-8571 x26902. If you have any questions about your rights as a study participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number). Thank you for your time and your participation in this important study!

[END. CODE AS A “294 – COMPLETE EMAIL NEEDED” IN CATI-CMS.]



9. Ok, thank you. The letter we sent contains all the information you need to complete your survey online. It includes instructions for accessing example medical device labeling, which we ask that you review prior to completing the survey. It also includes the web address for the online survey itself, as well as your username and password, both of which you will need to enter in order to access your secure online questionnaire.

9a. The survey will take approximately 30 minutes to complete. Once you have completed the survey we will send a check in the amount of [FILL INCENTIVE \$25/\$40/\$75] to thank you for participating. If you have any questions about the study, please feel free to call us at 1-800-334-8571 x26902. If you have any questions about your rights as a study participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number). The FDA will use the information you provide to create better guidance for the development and storage of medical device labels, so we thank you for your time and your participation in this important study!

[END. CODE AS A "295 – REMINDER CALL COMPLETED" IN CATI-CMS.]

10. It is really important that we speak with medical professionals like you. We would really like you to participate in the survey because the FDA wants to hear what medical professionals want related to device labeling. What questions or concerns do you have about participating?

INTERVIEWER: LISTEN TO QUESTIONS/CONCERNS & ADDRESS AS NEEDED.

- IF RESPONDENT AGREES TO PARTICIPATE AND Q3A=2, **GO TO Q4A.**
- IF RESPONDENT AGREES TO PARTICIPATE AND Q5=2 **GO TO Q6.**
- IF RESPONDENT REFUSES **CONTINUE TO Q11.**

11. Thank you for taking the time to speak with me today. If you change your mind, or have any additional questions or concerns please contact us at 1-800-334-8571 x26902. If you have any questions about your rights as a study participant, you can call RTI's Office of Research Protection at 1-866-214-2043 (a toll-free number).

11a. RECORD DETAIL ABOUT REFUSAL. WHAT DID R SPECIFICALLY SAY?

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[END. CODE AS A REFUSAL IN CATI-CMS.]