RTI INTERNATIONAL

3040 Cornwallis Road ▪ PO Box 12194 ▪ Research Triangle Park, NC 27709-2194 ▪ USA
Telephone 919.541.6000 ▪ Fax 919.541.5985 ▪ www.rti.org

Attachment B: In-Person Consent Form

FDA Medical Device Labeling Study
Participant Informed Consent
In-Person Interview

You are invited to participate voluntarily in this interview, which is being conducted by RTI International, a not-for-profit research firm, for the U.S. Food and Drug Administration (FDA). The purpose of this research study is to determine what information should be provided with medical devices, and how that information should be organized and communicated. We are asking more than 600 health care professionals across the country to assess whether the format and content of example device labeling is clear, understandable, useful, and user-friendly. The project findings will help inform FDA's approach to standardizing device labeling. You are being asked to participate because your name was included on a list of licensed medical professionals.

The interview and discussion will take approximately 60 minutes. There are no right or wrong answers to the questions we ask—we just want to ask your opinions about the sample medical device label we are providing for your review.

Your participation in this study is voluntary and you may choose not to answer any question. Your participation will be kept private to the fullest extent allowed by law by the research team, and the information you give us will be combined with the responses of others in a summary report that does not identify you as an individual. We would like to audio record this interview. The recording will be deleted after the project is over. Are you OK with my recording the interview? (___ Yes; ___No). Although we expect there to be no risks for your participation in this study, you will not directly benefit from participating either. However, your input will help the FDA improve upon the clarity of future medical device labels and you will be paid [FILL: INCENTIVE AMOUNT] in appreciation for your time.

If you have any questions about the study you may telephone Stacey Weger at 1-800-334-8571 ext. 26902. If you have any questions about your rights as a research participant in this study, you may contact the Office of Research Protection at RTI International at 1-866-214-2043, a toll-free number.

The above document describing the benefits, risks and procedures for this research study has been explained to me. I agree to participate.

Signature of participant_____ Date ___/___/_____

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

Signature of Person Who Obtained Consent_____ Date ___/___/_____

OMB No. 0910-XXXX
Exp. Date:

Public Reporting burden of this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:
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