RTI International is a trade name of Research Triangle Institute.

Attachment B: In-Person Consent Form

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

You are invited to participate in a research project that is being conducted by the U.S. Food and Drug Administration (FDA). Your participation in this study is voluntary. The purpose of this research project is to compare the labeling for medical devices as it currently exists with labeling for the same medical device prepared using a format we are considering to standardize medical device labeling. The study findings will help inform FDA's approach to standardizing content found in medical device labeling so that it communicates most effectively the critical information users need and want to know. You are being asked to participate because you have experience with at least one of the medical device types being tested in this study.

The study will take approximately 90 minutes. You will be presented with a series of scenarios one might encounter in the course of using one or more of the devices being tested and asked questions related to the scenarios. Specifically, we will ask you to identify the labeling section or sections that contain the information needed to answer each question. After you have completed all the scenarios for each device, we will ask you some specific questions about aspects of labeling not included in the scenarios.

Your participation in this study is voluntary and you may choose not to respond to any scenario. Your participation will be kept private to the fullest extent allowed by law by the research team. Your responses 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 will be no risks from your participation, you will not directly benefit either. However, your input will help the FDA improve the clarity of future medical device labeling and you will be paid [FILL: INCENTIVE AMOUNT] via check in appreciation for your time.

If you have any questions about the study or questions about your rights as a research participant in this study you may telephone Mary Brady at 1-301-796-6089.

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, expires xx/xx/xxxx

Public Reporting burden of this collection of information is estimated to average 90 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:

Department of Health and Human Services

Food and Drug Administration

Office of Chief Information Officer

Paperwork Reduction Act Staff

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