Appendix V

OMB No: 0910-0497 **Expiration Date: 10/31/2020**

Paperwork Reduction Act Statement: According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0497. The public reporting burden for this collection of information has been estimated to average 5 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.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.

Nutrition Facts Label Campaign Focus Groups (Formative Research and Stimulus Testing) – Phase 2 Consent Form

Purpose:

- This study is about the new Nutrition Facts label.
- The U.S. Food and Drug Administration (FDA) is conducting this study to create educational materials about the Nutrition Facts label.

What is involved:

- You are being asked to be part of a focus group discussion.
- We will ask you some questions about how to make people aware of the new Nutrition Facts label.
- The focus group discussion will take approximately 90 minutes.

Confidentiality:

- Your name and information will be kept secure to the extent allowed by law.
- We will video record the discussions. We will keep the recordings secure and destroy them by 2022.
- What you say will not be connected with your name. We will report our results in a summary report. We may use quotes you say in our report, but we won't use your name.

Risks:

- It is your choice to do this focus group discussion.
- You can stop participating at any time.
- There are no known risks for participation in this research activity.

Benefits:

- There are no direct benefits to you for participating in this study.
- You will be helping with an important research project.

Questions:

- If you have questions about the project you may call the RTI Project Director, Claudia Squire, at RTI at cms@rti.org and 919-541-6613.
- If you have any questions or complaints about your rights as a research subject, please contact FDA's IRB, Research Involving Human Subjects Committee, at RIHSC@fda.hhs.gov and 301-796-9605.

You will receive $75 cash as a token of appreciation for your participation in the discussion.
If you agree to participate, please sign below.

I have read and understand the statements above. I consent to participate in this focus group.

_____ _____

Participant's signature Date