**Appendix C. FDA CTP Exchange Lab Informed Consent Information (POTENTIAL USERS)**

**IRB Protocol No. 2019-CTP-011**

**OMB No. 0910-0697**

**Exp. Date: 12/31/2020**

**Title: FDA CTP Exchange Lab Syndication Study—Potential Users**

**Welcome to the FDA Center for Tobacco Products (CTP) Exchange Lab Survey!**

Please read this form carefully. **You must submit this form by clicking the “Start survey now” button at the bottom of this page before you can take part in the study.**

**Introduction: About this study**

The purpose of this research study is to see how satisfied you are with FDA CTP’s Exchange Lab and to learn a little bit about you.

This 8-minute, anonymous, survey is completely voluntary and you may quit, without penalty, at any time. One item, at the end of the survey, requests your name and email address if you would like to be contacted for a subsequent study.If you decide to provide your name and email address, these items will remain separate from your survey responses. The research team will not use your contact information for any purpose other than contacting you about the future study. Your contact information will not be shared with others.

**Who will see the information I provide during this study?**

We will take care to protect your privacy. Your answers will be kept private to the extent allowable by law. That means we will not share your answers with anyone outside the study unless it is necessary to protect you, or if required by law. Any personal information that identifies you will be kept separate from your survey responses. No one will know what answers you gave us.

We will not share your identity in any report or presentation.

We will keep your answers for three years after the end of the study. The data will be stored on a password-protected computer. Three years after the end of the study, we will destroy all of the data by permanently deleting records.

**What are the risks and benefits of being in this study?**

There are no foreseeable risks or discomforts by participating in this survey. It is possible that you may not want to answer some questions in the survey. If you do not want to answer a question, you may skip that question or choose the “Prefer not to answer” response. The study is not expected to directly benefit you. However, your answers will help CTP Exchange Lab better serve the needs of its content syndication users.

**Will I be paid for being in this study?**

No, there is no payment for participating in this study. Completing the survey for this study is a voluntary effort.

If you have any questions about this survey, or any problems completing the survey, please contact Dr. Everly Macario at IQ Solutions, Inc., at 224-244-3965 or EMacario@IQSolutions.com, working on behalf of CTP.

The Institutional Review Board (IRB) at the Food and Drug Administration has reviewed this research. FDA IRB is a group of people who are responsible for ensuring that the rights of participants in research are protected. FDA IRB is not involved in this study but may review the records of your participation in this research to ensure that proper procedures were followed.

If you have questions about your rights as a study participant or concerns about how you are treated in the study, you may contact FDA IRB at 301-796-9605 or RIHSC@fda.hhs.gov. When contacting FDA IRB, please reference protocol #2019-CTP-011.

**If you click on “Start survey now,” you are voluntarily agreeing to take part in this survey. Click one of the options below.**

I have read, understand, and had time to consider all the information above. My questions have been answered, and I have no further questions.

\_\_\_\_\_ **Start survey now** / I voluntarily agree to participate in this study.
[Go to Screener Questions]

\_\_\_\_\_ **Exit survey** / I do not want to participate in this study. [TERMINATE SURVEY; GO TO TERMINATION TEXT 1]

[TERMINATION TEXT 1:] You have indicated that you do not want to participate in the FDA CTP Exchange Lab Survey and will now exit the survey. If you decide later that you would like to participate, use the same email invitation to access the survey. Thank you for your time!

**Paperwork Reduction Act Statement:** The public reporting burden for this information collection has been estimated to average 5 minutes per response to complete this form (the time estimated to read and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRAStaff@fda.hhs.gov.