RTI INTERNATIONAL

Office of Research Protection

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APPROVAL

March 16, 2022

Matthew Eggers
919-990-8380, x28380
meggers@rti.org

Dear Matthew Eggers:

On 3/16/2022, the IRB reviewed the following submission:

Type of Review:	Initial Study
Title:	Formative Research Support: Outcomes and Awareness Measurement Research
Investigator:	Matthew Eggers
IRB ID:	STUDY00021925
Funding Source:	FDA Ctr Tobacco Products
Customer/Client Name:	FDA Ctr Tobacco Products
Project/Proposal Number:	0217597.008
Contract/Grant Number:	75F40120A00017
IND, IDE, or HDE:	None

The IRB approved the study on 3/16/2022. Any changes to the approved study protcol or documents must be submitted to the IRB as a modification for review and approval prior to implementation. Within 30 days of study completion, you should request to close the study in IRB Express. You can submit a modification or study closure by navigating to the active study and clicking Create Modification / CR.

In conducting this protocol, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Please be aware that before any research with human subjects can begin, the study team is required to submit a modification to provide documentation that this FDA-CTP funded study has in place an approved QMP. In this modification, the study team must: 1) revise their response to Section 23 of the protocol template, to indicate that this FDA-CTP funded study has a QMP; and 2) upload a scanned copy of the QMP signature page or equivalent documentation of approval to the "Local Site Documents" section of IRB Express.

Sincerely,
The RTI Office of Research Protection