



Office of Research Protection

3040 Cornwallis Road ■ PO Box 12194 ■ Research Triangle Park, NC 27709-2194 ■ USA
Telephone 919-316-3358 ■ Toll Free 1-866-214-2043 ■ Fax 919-316-3897 ■ www.rti.org

NOT HUMAN RESEARCH DETERMINATION

August 19, 2020

Jennifer Duke
919-485-2669, x22669
jduke@rti.org

Dear Jennifer Duke:

On 8/19/2020, the IRB reviewed the following protocol:

Type of Review:	Initial Study
Title:	Hornik Study
Investigator:	Jennifer Duke
IRB ID:	STUDY00021223
Funding Source:	FDA Ctr Tobacco Products
Customer/Client Name:	FDA Ctr Tobacco Products
Project/Proposal Number:	0215534.001
Contract/Grant Number:	HHSF223201610032I
IND, IDE, or HDE:	None

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS regulations.

Although RTI IRB oversight of this activity is not required, this determination applies only to the activities described in the IRB submission and may not apply should any changes be made. If the nature or scope of the activity changes and there are questions about whether the revised activities constitute human subjects research, you should contact the IRB to discuss whether a new submission and determination is necessary.

Sincerely,
The RTI Office of Research Protection