Active Protocol FDA CTP Public Education Materials Study	IRB	Case Number 18-001CTP	
Sponsor Navarro, Mario	**Organization** CTP-White Oak	**Email** mario.navarro@fda.hhs.gov	**Phone**
Approved		**Date Submitted** 1/5/2018	**Expiration Date**

Doc Ver: 281-311

Laboratory Not in List

Laboratory: N/A

Recommendations

1/9/2018 IRB Admin:

Your research study, RIHSC# 18-001CTP, does not require Research Involving Human Subjects Committee (RIHSC) review and approval because it is exempt from the requirements of 45 CFR §46.101b(2). Below, RIHSC has provided recommendations which we think may improve your study documents. There is no need to submit an amendment for your responses to these recommendations at this time. In the future if you propose changes that you think have the potential to alter the exemption status of this study, discuss the changes with your liaison and decide together if you need to file an amendment. When you file an amendment, please include a narrative describing any changes made since the last submission.

Although this research activity is exempt from RIHSC oversight, the Sponsor and the Principal Investigator (PI) are not relieved of the responsibility to ensure that the research activity involving human subjects is conducted in an ethical manner. It is the Sponsor and PI's responsibility to safeguard the rights and welfare of each human subject participating in the research activity. You are reminded of your obligations under applicable federal, international, state, local laws regulations, and policies that provide additional protection for human subjects participating research.

Additional relevant documents and information, such as the Belmont Report and links to the Code of Federal Regulations citations and OHRP's policy and guidance, as well as a copy of the RIHSC Standard Operating Policies and Procedures, may be found on the RIHSC webpage at
http://inside.fda.gov:9003/OC/OfficeofScientificMedicalPrograms/OfficeofScientificIntegrity/ucm336966.htm
For your reference, the regulation containing the Department of Health and Human Services general requirements for informed consent (45 CFR 46.116) can be found at http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46.

Comment:
Please consider a review for grammatical consistency.

Liaison: Survey to be completed on an ipad at professional conferences; no PII collected in adults, for consideration for an exempt study. 1/5/2018

Point of Contact

None

Inventory Requests

None

Associated Researchers

None

Associated Registrations

None

Project Information [45 CFR 46 101 (b)(2)]

Name of Principal Investigator

Mario Navarro

My project involves only ADULTS (18 years and older or as defined by state requirements for age of majority).

Yes

AND this Project uses only:

Survey procedures

Please check the items that also apply to this project:

Information is recorded in such a manner that subjects cannot be identified, directly or through identifiers.

Project Documents [45 CFR 46 101 (b)(2)]

Please attach the study protocol, including either focus group or survey questions.

CXXUsersXMario.NavarroXDesktopXPublic_Education_Materials_Study_1_5_18_Clean.zip

Please attach information on who will be conducting the interviews/focus group testing including documentation that the person(s) has been trained.

CXXUsersXMario.NavarroXDesktopXApp_E_PE_Materials_Study_CITI_CERTIFICATES_AND_CVs.zip

If applicable, please attach the following below:

Recruitment and/or Advertisement Information

CXXUsersXMario.NavarroXDesktopXFinal_Public_EducationXPublic_Education_Materials_Study_1_5_18_CleanXApp_A_PE_Materials_Study_CONFERENCES.docx

Please indicate if you will be including any of these documents and attach any relevant documents accordingly.

N/A, Please explain:

Comment: *Survey and consent are entirely online. Participants are offered a hardcopy of informed consent if they ask.*

Upload center specific review materials.

Study Data [45 CFR 46 101 (b)(2)]

Please indicate any sources of data

Survey Questions

Confidentiality of Data (Please check all that apply and attach applicable documentation)

No personally identifiable information will be sent to FDA (please attach documentation).

Storage of Data (please check all that apply)

All electronic data will be maintained in a secure manner with limited authorized access

Please check and answer all that apply:

Written documentation will be transferred to a locked storage facility and will be destroyed (please indicate after how many years)

Comment: *For 3 years the data will be stored.*

Sponsor Attestation

Carefully read the following statement and indicate by checking the box that you agree. This protocol cannot be submitted without affirming the statement.

I understand that if any changes are proposed for the study, I will need to resubmit the materials to the RIHSC to make sure none of the proposed changes alter the basis for the above exemption.

Please have your FDA Sponsor (or if you are the Sponsor) sign-off this submission by clicking the red "Sponsor E-Signature" button located at the bottom right of the screen. Please note your protocol must be complete.

This protocol has been fully reviewed.

Transaction History

1/5/2018 3:19 PM	PI E-Signatured	mario.navarro
1/5/2018 3:24 PM	Submit to IRB Administrator	carolyn.dresler