

Marisa Greenberg <mgreenberg@rescueagency.com>

FW: Congrats! FDA IRB NON-Engagement Determination

1 message

Navarro, Mario <Mario.Navarro@fda.hhs.gov>
To: Marisa Greenberg <mgreenberg@rescueagency.com>

Wed, Aug 28, 2019 at 7:53 AM

From: Lacorte, Lester (Jao)
Sent: Tuesday, July 30, 2019 6:03 PM
To: Navarro, Mario <Mario.Navarro@fda.hhs.gov>
Cc: CTP_RIHSC <CTP_RIHSC@fda.hhs.gov>; Dresler, Carolyn <Carolyn.Dresler@fda.hhs.gov>; Walker, Matthew <Matthew.Walker@fda.hhs.gov>
Subject: RE: Congrats! FDA IRB NON-Engagement Determination

Study title: 2019-CTP-073 - *“Developing Brand and Creative Concepts Designed to Prevent AI/AN Youth Tobacco Use”*

RE: FDA IRB NON-Engagement Approval Determination

Hi Mario,

Congratulations! On 7/17/2019, the FDA IRB determined that your study does not require FDA IRB review or an IRB Authorization Agreement (IAA). FDA's involvement does not constitute engagement in the research for purposes of §45 CFR Part 46.

For further assistance, feel free to consult with CTP RIHSC Program Advisors during regular office hours. Or for more information, go to: S:\OS\RIHSC for Sponsors

Thanks,

Jao Lacorte, MD, CCRP

FDA Medical Officer

Center for Tobacco Products
Office of Science
U.S. Food and Drug Administration
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From: Dresler, Carolyn
Sent: Tuesday, July 30, 2019 5:20 PM
To: Navarro, Mario <Mario.Navarro@fda.hhs.gov>; Walker, Matthew <Matthew.Walker@fda.hhs.gov>
Cc: CTP_RIHSC <CTP_RIHSC@fda.hhs.gov>
Subject: FW: Determination form request accepted by HSP Executive Office

Yippee!

From: SharePointAlert@sharepoint.fda.gov <SharePointAlert@sharepoint.fda.gov>
Sent: Tuesday, July 30, 2019 4:03 PM
To: Dresler, Carolyn <Carolyn.Dresler@fda.hhs.gov>; Navarro, Mario <Mario.Navarro@fda.hhs.gov>
Cc: Cox, Rhondalyn <Rhondalyn.Cox@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>; Ulisney, Karen <Karen.Ulisney@fda.hhs.gov>; Mokhtarzadeh, Maryam <Maryam.Mokhtarzadeh@fda.hhs.gov>
Subject: Determination form request accepted by HSP Executive Office

SharePoint Workflow Notification

A determination form request has been concurred by the HSP Executive Officer. To access the form, you may click the link below, with the following comments:

Determination Form Type: FDA Engagement Determination Form

[96-Determination-CTP-2019-07-17](#)

Protocol Title: Developing Brand and Creative Concepts Designed to Prevent AI/AN Youth Tobacco Use
FDA Project Lead: Mario Navarro;
HSP Liaison: Carolyn Dresler;

Comments:

Based on the information submitted, the research activity under study title "Developing Brand and Creative Concepts Designed to Prevent AI/AN Youth Tobacco Use)" does not require FDA IRB review or an IRB Authorization Agreement (IAA). FDA's involvement does not constitute engagement in the research for purposes of 45 CFR part 46. This finding does not relieve the FDA staff involved in the activity from any responsibilities and requirements in other applicable regulations, statutes, or policies. If changes are proposed to ongoing nonexempt human subject research that could make FDA engaged in the research, the HSP Liaison, in collaboration with the FDA Project Lead, must complete a new FDA determination form with supporting information to request confirmation of the determination from the HSP Executive Officer.

For applicable FDA Standard Operating Policies and Procedures and Staff Manual Guide 9001.4 refer to the SharePoint site for Human Subjects Research Conducted or Supported by the FDA at: <http://sharepoint.fda.gov/orgs/OC-OCS/HSR/IAA/SOP/Forms/AllItems.aspx>.