Dear Mario Navarro,

Your protocol **18-058CTP** has been reviewed with a determination made. The protocol can be found under your **My Research** tab. Please see the comments below or in the comments tab for additional information regarding your application.

Please log into the SIPS system at https://sips.fda.gov and proceed to PI-Dashboard to review this submission.

If you have any additional questions, please contact RIHSC at RIHSC@fda.hhs.gov.

Comments: 11-2-18 IRB Admin:

Your research study, RIHSC# 18-058CTP, 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 one recommendation 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/ProgramsInitiatives/CommitteesWorkgroups/ResearchInvolvingHumanSubjectsCommitteeRIHSC/default.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: Consider in the informed consent adding a contact for questions about rights as a research participant in addition to questions about the study. As it stands, those questions would probably go to the PI, but consider if the PI is the best person for those questions; if not, you might add another contact.

Best Regards,

RIHSC SIPS Support

Email Reference: [7ca7b58da93af30391919b9ccc92166d]
Time Sent: [11/2/2018 11:25 AM]