Dear Chaunetta Jones,

Your recent IRB registration **16-054CTP** has been **Approved** and can be found under your **myResearch** tab.

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

Comments: 8-29-16
Your research study, RIHSC# 16-054CTP, 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). In the future if you propose changes that might alter the exemption status of this study, you must file an amendment. At that time, please also include a narrative describing any changes made since the original 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.

Best Regards,

RIHSC SIPS Support

Email Reference: [7ca7b58da93af30391919b9ccc92166d]
Time Sent: [8/29/2016 5:13 PM]