From: SharePointAlert@sharepoint.fda.gov
To: Dresler, Carolyn; Dineva, Nasi
Cc: Cox, Rhondalyn; Miller, Mark S (OC); O"Shaughnessy, Jacqueline A; Mokhtarzadeh, Maryam
Subject: Determination form request accepted by HSP Executive Office
Date: Monday, May 06, 2019 12:11:51 PM

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: Exempt Research Determination Form

78-Determination-CTP-2019-05-01

Protocol Title: FDA CTP Exchange Lab Syndication: Potential Users Study
FDA Project Lead: Atanaska Dineva;
HSP Liaison: Carolyn Dresler;

Comments:

Based on the information submitted, the research study title "FDA CTP Exchange Lab Syndication: Potential Users Study" does not require FDA IRB review and approval because it is exempt from the requirements of 45 CFR 46 [45 CFR 46.104(d)(2)(ii)]. If changes are proposed to ongoing human subjects research that could affect its exempt status, the HSP Liaison, in collaboration with the FDA Project Lead, must complete a new exemption determination form with supporting information to request confirmation of that determination from the HSP Executive Officer. Although this research activity is exempt from FDA IRB oversight, all of FDA's human subjects research activities, regardless of whether the research is subject to regulation under the Common Rule or FDA regulations, will be guided by the ethical principles of respect for persons, beneficence, and justice, in accordance with the Belmont Report.
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.