MEMORANDUM
FDA Human Subject Protection Program Management Staff

DATE: 11/21/2022

FROM: Human Subject Protection (HSP) Executive Officer, Office of the Chief Scientist (OCS)

TO: Paula Rausch, CDER**,** FDA Project Lead
CC: Jill Brown, CDER, HSP Liaison

SUBJECT: FDA Protocol Number: 2023-CDER-021

STUDY TITLE: FDA CDER Rapid Message Testing with Consumer and Healthcare Professional Panels

SUBMISSION TYPE: Exempt Research Determination

Based on the information submitted, the research study title "FDA CDER Rapid Message Testing with Consumer and Healthcare Professional Panels" does not require FDA IRB review and approval because it is exempt from the requirements of 45 CFR 46.104(d)(2)(i). 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: https://fda.sharepoint.com/sites/OC-intranet-OC-OCS-Human-Subject-protection/.

If you have questions, or would like further information, please do not hesitate to contact the Human Subject Protection Program Management Staff in the Office of the Chief Scientist by email at HSPPMS@fda.hhs.gov.