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Memo

Date: November 29, 2023

To: Cynthia Robins, Project Director

From: Sharon Zack, Westat IRB Administrator Sharon Zack

Subject: **Initial Approval of FDA OMHEE FG - Racial and Ethnic Differences in Consumer Reporting of Adverse Events in MedWatch/FAERS, Project Number 6781.26 FWA 00005551**

As Administrator of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **FDA OMHEE FG - Racial and Ethnic Differences in Consumer Reporting of Adverse Events in MedWatch/FAERS, Project Number 6781.26.** The Westat IRB reviews all studies involving research on human subjects. The Office of Minority Health and Health Equity (OMHHE) at FDA funds this project.

The purpose of conducting 12 online focus groups is to explore the perceptions of, attitudes about, and access to adverse event reporting using MedWatch among racial and ethnic minority patients and consumers.

Per [45 CFR 46.104(d) (2)], and the information provided, this research includes interactions such as education tests (cognitive, diagnostic, aptitude, achievements), survey or interview procedures, or observation of public behavior (e.g., visual or audio recording), if at least one of the following criteria are met:

- Information recorded cannot be readily linked back to subjects, or
- Any information disclosed outside of the research would not reasonably place subjects at risk of harm, or
- Identifiable information recorded, with limited IRB review for protecting privacy and confidentiality.

This project is exempt from further IRB review.

Please note the following:

- **IRB approval is required before any new or modified research activities are conducted or when there is a problem involving risks to human subjects.**
- Upon learning of an incident, you must contact the Westat IRB Office within 24 hours via telephone (301-610-8828) or email (IRB@westat.com).
- Notify our office when your project is over.

cc: Institutional Review Board
Alicia Sutherland