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Memo

Date: July 12, 2022

To: Sophia Tsakraklides, Project Director

From: Sharon Zack, Westat IRB Administrator Sharon Zack

Subject: **Initial Approval of FDA Sunscreen Study, Project Number 6781.12**
FWA 00005551

As Administrator of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **FDA Sunscreen Study, Project Number 6781.12**. The Westat IRB reviews all studies involving research on human subjects. The Food and Drug Administration funds this study.

The purpose of the research is to collect qualitative data about consumer decision making regarding sunscreens.

Westat will conduct semi-structured cognitive interviews to collect the following:

- How consumers read and interpret sunscreen label information
- Consumer purchase decisions based on sunscreen label information
- Consumer feedback to improve sunscreen labels

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 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.

Therefore, 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