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Research Corporation

Memo

Date: April 8, 2019

To: Thea Zimmerman, Project Director

From: Sharon Zack, Westat IRB Administrator *Sharon Zack*

Subject: **Initial Approval of WIC Nutrition Risk Study, Project Number 6647.01
FWA 00005551**

As Administrator of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **WIC Nutrition Risk Study, Project Number 6647.01**. The Westat IRB reviews all studies involving research on human subjects. The USDA Food and Nutrition Service funds this study.

The purpose of this project is to understand the WIC nutrition risk assessment process including ways in which WIC clinics tailor participant benefits to address the results of the assessment.

Westat will conduct the evaluation of the WIC nutrition risk process including the following activities:

- Conduct a cognitive test of all data collection instruments
- Conduct a field test of all site visit protocols
- Select WIC State Agencies (SAs), Local Agencies (LAs), and WIC clinics from across the U.S.
- Recruit and enroll study participants
- Design and administer Local Agency web survey, observation and in-depth interview guides
- Conduct site visits at WIC clinics to observe clinic operations and the nutrition risk assessment process as well as in-depth interviews with study participants
- Collect state, local agency, and clinic documents/guidelines relevant to the nutrition risk assessment.
- Process and analyze collected data and write study reports
- Prepare and deliver to FNS final reports

Per [45 CFR 46.104(d) (2)], and the information provided, this research includes interactions such as education tests (cognitive, diagnostic, aptitude, achievements), survey procedures, interview procedures or observation of public behavior (including 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 disclosure outside of the research would not reasonably place subjects at risk of harm, or
- Identifiable information recorded, with limited IRB review for privacy and confidentiality protection.

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
Frank Bennici