

An Employee-Owned Research Corporation

Memo

Date: April 20, 2021

To: Janice Machado, Project Director

From: Sharon Zack, Westat IRB Administrator

Subject: Initial Approval of WIC ITFP Study, Project Number 6798

FWA 00005551

As Administrator of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **WIC ITFP Study, Project Number 6798.** The Westat IRB reviews all studies involving research on human subjects. The Food and Nutrition Service of the USDA, will fund this study.

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This is an extension of a current project to follow up with mothers/caregivers of children four years after the end of the child's WIC age eligibility. This includes collecting data about the WIC program and policy, as well as the nutrition and wellbeing of children up to the month of their ninth birthday.

This revision seeks to encompass two activities:

- 1. Year 9 Follow-up Study (Y9FU) Study extends the data collection timeframe of WIC ITFPS-2 up to 9 years of age for study children.
- 2. Lost to Follow-up Study or L2FU Study involves examining WIC administrative data to gather programmatic administrative data on former WIC ITFPS-2 participants.

Westat will oversee data collection including the following:

- Updated contact information from current participants
- Year 9 Interview Telephone Survey
- Year 9 Replicate Dietary Intake Interview
- Height/Weight Measurements of youth at WIC Site or Provider's Office
- Administrative Data on Lost to Follow-up (L2FU) Study Participants

Per 45 CFR 46, IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) 1]. This study can be considered minimal risk and is approved under expedited authority.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review before April 20, 2022.
- 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 IRB Office within 24 hours via telephone (301-610-8828) or email (IRB@westat.com).
- For questions regarding this memo, contact Sharon Zack at 301-610-8828 or sharonzack@westat.com.

cc: Institutional Review Board Frank Bennici