ClinicalTrials.gov Title Page

Document: Study Protocol

Official Study Title: The Effect of Supplemental Nutrition Assistance Program-Education on the Dietary Intake of Low-income Indiana Participants

NCT #: NCT03436784

Document Date: September 28, 2015

APPLICATION TO USE HUMAN RESEARCH SUBJECTS

Purdue University
Institutional Review Board

1. Project Title: The effect of Supplemental Nutrition Assistance Program-Education on the dietary intake of low-income Indiana participants

2. Full Review ☐ Expedited Review ☒

3. Anticipated Funding Source: AgSEED - Agricultural Research and Extension leading to Economic Development in Indiana Agriculture and Rural Communities

4. Principal Investigator *[See Policy on Eligibility to serve as a Principal Investigator for Research Involving Human Subjects]*:
Name and Title Department, Building, Phone, FAX, E-mail address

Dr. Heather A. Eicher-Miller, Assistant Professor, Department of Nutrition Science, Purdue University, Stone Hall Room G-2, (765) 494-6815, Fax: (765) 496-9606, heicherm@purdue.edu

5. Co-investigators and key personnel *[See Education Policy for Conducting Human Subjects Research]*:
Name and Title Department, Building, Phone, FAX, E-mail address

Angela R. Abbott, MA, RD, CD, Program Leader and Assistant Director, Health and Human Sciences Extension, Purdue University, Matthews Hall Room 110, (765) 494-8252, Fax: (765) 494-0674, abbottar@purdue.edu

Melissa K. Maulding, MS, RD, Nutrition Education Programs Director, Health and Human Sciences Extension, Purdue University, Matthews Hall Room 108, (765) 496-6849, Fax: (765) 494-0674, mmaulding@purdue.edu

Rebecca L. Rivera, **MPH** Graduate Student, Department of Nutrition Science, Purdue University, Stone Hall, (765) 496-2757, Fax: (765) 496-9606, rcusack@purdue.edu

Ashley G. Jacobs, MS, RD, Graduate Student, Department of Nutrition Science, Purdue University, Stone Hall, (765) 496-2747, Fax: (765) 496-9606, jacobs38@purdue.edu

Breanne Wright, MS, Graduate Student, Department of Nutrition Science, Purdue University, Stone Hall, (765) 496-2747, Fax: (765) 496-9606, wrigh197@purdue.edu

Key personnel:

Indiana Nutrition Education Program Educators, Health and Human Sciences Extension, Purdue University, Matthews Hall Room 108, (765) 496-6849, Fax: (765) 494-0674, mmaulding@purdue.edu
Note: NEP Educators have completed CITI Training as a requirement for working for Extension

6. Consultants *[See Education Policy for Conducting Human Subjects Research]*:
Name and Title Department, Building, Phone, FAX, E-mail address

7. The principal investigator agrees to carry out the proposed project as stated in the application and to promptly report to the Institutional Review Board any proposed changes and/or unanticipated problems involving risks to subjects or others participating in the approved project in accordance with the HRPP Guideline 207 Researcher Responsibilities, Purdue Research Foundation-Purdue University Statement of Principles and the Confidentiality Statement. The principal investigator has received a copy of the Federal-Wide Assurance (FWA) and has access to copies of 45 CFR 46 and the Belmont Report. The principal investigator agrees to inform the Institutional Review Board and complete all necessary reports should the principal investigator terminate University association.

_____ _____

Principal Investigator Signature Date

8. The Department Head (or authorized agent) has read and approved the application. S/he affirms that the use of human subjects in this project is relevant to answer the research question being asked and has scientific or scholarly merit. Additionally s/he agrees to maintain research records in accordance with the IRB's research records retention requirement should the principal investigator terminate association with the University.

_____ _____

Department Head *(printed)* Department Name

_____ _____

Department Head Signature Date

9. This project will be conducted at the following location(s): (please indicate city & state)
   - ☐ Purdue West Lafayette Campus
   - ☐ Purdue Regional Campus (Specify): _____
   - ☒ Other (Specify): Indiana Nutrition Education Program class locations throughout Indiana, these may include: Emergency food distribution centers; Supplemental Nutrition Assistance Program (SNAP) offices; Women, Infant, and Children Program (WIC) offices; participant homes

10. If this project will involve potentially vulnerable subject populations, please check all that apply.
   - ☐ Minors under age 18
   - ☐ Pregnant Women
   - ☐ Fetus/fetal tissue
   - ☐ Prisoners Or Incarcerated Individuals
   - ☐ University Students (PSYC Dept. subject pool ___)
   - ☐ Elderly Persons
   - ☒ Economically/Educationally Disadvantaged Persons
   - ☐ Mentally/Emotionally/Developmentally Disabled Persons
   - ☐ Minority Groups and/or Non-English Speakers
   - ☐ Intervention(s) that include medical or psychological treatment

11. Indicate the anticipated maximum number of subjects to be enrolled in this protocol as justified by the hypothesis and study procedures: 800 (400 for control group and 400 for experimental group)

12. This project involves the use of an **Investigational New Drug** (IND) or an **Approved Drug For An Unapproved Use**.
   ☐ YES ☒ NO
   Drug name, IND number and company: _____

13. This project involves the use of an **Investigational Medical Device** or an **Approved Medical Device For An Unapproved Use**.
   ☐ YES ☒ NO
   Device name, IDE number and company: _____

14. The project involves the use of **Radiation or Radioisotopes**:
   ☐ YES ☒ NO

15. Does this project call for: (check-mark all that apply to this study)
   - ☐ Use of Voice, Video, Digital, or Image Recordings?
   - ☒ Subject Compensation? Please indicate the maximum payment amount to subjects. $100
     Purdue's Human Subjects Payment Policy Participant Payment Disclosure Form
   - ☐ VO2 Max Exercise?
   - ☐ More Than Minimal Risk?
   - ☐ Waiver of Informed Consent?
   - ☐ Extra Costs To Subjects?
   - ☐ The Use of Blood? Total Amount of Blood _____ Over Time Period (days) _____
   - ☐ The Use of rDNA or Biohazardous materials?
   - ☐ The Use of Human Tissue or Cell Lines?
   - ☐ The Use of Other Fluids that Could Mask the Presence of Blood (Including Urine and Feces)?
   - ☐ The Use of Protected Health Information (Obtained from Healthcare Practitioners or Institutions)?
   - ☐ The Use of academic records?

16. Does investigator or key personnel have a potential financial or other conflict of interest in this study?

☐ YES ☒ NO

APPLICATION NARRATIVE

A. PROPOSED RESEARCH RATIONALE

The Supplemental Nutrition Assistance Program-Education (SNAP-Ed) is an educational program offered to SNAP participants. The Nutrition Education Program (NEP) through Purdue University Health and Human Sciences Extension administers SNAP-Ed in Indiana. The NEP curriculum comprises 10 lessons that are focused on nutrition and food resource management.

The goal of this study is to determine the efficacy of SNAP-Ed to improve the immediate and long-term dietary quality (using the Healthy Eating Index (HEI)), BMI (measured height and weight), and food security (using the 18-item US HFSSM) and how the provision of SNAP-Ed with the presence of other characteristics can mediate improvement in these outcomes. Previous studies by Dr. Eicher-Miller have shown significant improvements in household food security over short-term periods and a 1-year longitudinal period among Indiana NEP participants; however, the impact of SNAP-Ed on participants' dietary quality and BMI remains to be investigated. The hypothesis of this study is that dietary quality and food security will improve and BMI will remain steady over the short-term, and these improvements will be maintained over a 1-year, or "long-term", time frame in participants receiving SNAP-Ed compared to those not receiving SNAP-Ed. Results may be used as a basis for changes to the program or policies relevant to SNAP-Ed and other nutrition education programs throughout the US.

B. SPECIFIC PROCEDURES TO BE FOLLOWED

NEP educators are considered key personnel because they will have direct contact with study participants; however, they will not have any part in data entry, analysis, or dissemination of study results. NEP educators, employees of Purdue University Extension, across Indiana will help facilitate the study. NEP educators have completed CITI training as a requirement for employment through Purdue University Extension. Before recruiting study participants, participating NEP educators will attend training sessions facilitated by the co-investigators of the study. The training sessions will include instructions on how to interact with participants; answer questions related to the study; and protocol for administering surveys, measuring height and weight, keeping participant information private, and the use of identification numbers. The study goals and hypothesis will not be shared with the NEP educators in order to keep their work with the participants as unbiased as possible.

NEP educators will recruit study participants who are interested in participating in NEP. The details of recruitment are described in Section D. A screening survey determining eligibility will be administered in addition to an explanation of consent. After completion of the screening survey and consent process, NEP educators will randomize participants into one of two groups: control or experimental. The NEP educators will be assigned a random number using Excel and then listed in order from least to greatest according to their random number. The first half of the NEP educators will assign their first recruited participants to the experimental group. After the first assignment, they will alternate assigning participants to either study group in an "every other" participant fashion. The second half of the NEP educators will assign their first recruited participants to the control group. After the first assignment, they will also alternate assigning participants to either study group in an "every other" participant fashion. The control group will wait 1 year from taking the second survey before starting NEP lessons. The experimental group will start NEP lessons immediately. Participants in the experimental group must take at least the first 4 NEP lessons within a time period of 4 to 10 weeks. The NEP SNAP-Ed curriculum includes 10 lessons, and participants may take the additional 6 lessons if desired.

All participants will complete three 30 minute surveys throughout the study. Surveys will be administered by NEP educators using the Qualtrics Offline Application on their program-provided iPads or paper surveys. The first survey will be administered upon enrollment in the study. Participants in the experimental group will take the second survey after they have completed the first 4 lessons between 4 and 10 weeks after enrollment in the study. Control participants will take the second survey after 4 to 10 weeks with no lessons. Since participants will be recruited on a rolling basis, they will take surveys at different times within a designated time

period. The third survey will be administered to both groups 1 year after the second survey. Surveys are comprised of the US Household Food Security Survey Module from the United States Department of Agriculture Economic Research Service, questions querying household and individual level characteristics, and the Indiana Food and Nutrition Program Evaluation Tool.

Participants will also complete two 24-hour dietary recalls using the Automated Self-Assisted 24-hour recall (ASA-24) and one food frequency questionnaire (FFQ) using the Diet History Questionnaire II (DHQ II) at each data collection time point. Both instruments are online and complementary dietary assessment tools created by the National Cancer Institute and have a respondent and researcher website. Results will be analyzed by the researchers using the researcher website. One dietary recall and the FFQ may be administered by the NEP Educators immediately following the in person survey, or a link to complete the dietary recall and FFQ online will be emailed to the participant within 2 days, or the participant can request to complete the dietary recalls and FFQ over the phone with the co-investigators at Purdue within 7 days after completing the survey. A script will be provided for the Purdue researchers to administer the dietary recalls and FFQ. The completion of the dietary recalls and the FFQ is necessary to perform complex modeling techniques for estimating *usual* dietary intake. The program that administers the dietary recalls assists participants through the recall process using an animated guide with audio and visual cues. Previous research has shown that the majority of Indiana SNAP-Ed participants have a computer with high-speed Internet connection in their home or residence. Participants without email, without access to a computer with internet, or with limited computer skills will be instructed to complete the assessments via telephone with assistance from researchers. If assistance from researchers is needed via telephone, participant identifying information will not be collected at that time. Participants will be identified only by their participant identification number, which they will receive upon enrollment in the study. Participants will provide days and time frames over the following week when they will be available to complete the dietary assessments over the phone with Purdue researchers. In addition, participants may call the co-investigator's Purdue office phone number any time after the survey for assistance with completing the dietary assessments. If the first dietary recall and FFQ have not been completed within 4 days after the survey, researchers will call the participant no more than once per day to complete the first dietary recall and FFQ over the phone at that time or to set up appointments to complete the dietary recalls and FFQ over the phone with researchers within the 7 days after completing the in person survey. The second dietary recall should be completed 24 hours after the first dietary recall at the earliest but before 9 days after completing the in person survey. Participants will have the same options as described above to complete the second dietary recall.

In addition to the survey, dietary recalls, and FFQ, NEP educators will take height and weight measurements on each participant at each assessment time point. Weights will be measured using the SECA 869 mobile medical flat scale with remote display. Heights will be measured using the SECA 213 mobile stadiometer. This weight scale and stadiometer are research grade measurement tools. Height and weight measurements will be taken following the Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES) anthropometry manual guidelines. Height and weight measurements will be completed in a private setting or privacy screens will be used. Only the NEP educators will be able to see the measurements. Three measurements will be taken at each assessment time point in order to calculate an average. Participants will be allowed to know their measurements upon request at the time of measurement. Researchers will use these measurements to calculate BMI.

An in person survey, two dietary recalls, one FFQ, and height and weight measurements will be completed for each participant at each of the three assessment time points. The first and third assessments will cover a reference period the past 12 months, while the second assessment will cover the past 30 days. Participants randomized to the control group will be provided the opportunity to complete the SNAP-Ed program at the completion of the study.

C. SUBJECTS TO BE INCLUDED

Describe: The inclusion criteria for the study population includes: an interest in taking NEP lessons, willingness to wait 1 year to start NEP lessons, eligibility for SNAP, age of at least 18 years, not pregnant, living in a household located in Indiana, ability speak and read English, willingness to complete three 30 minute surveys at the designated time intervals, willingness to provide height and weight measurements, willingness to complete one 30 minute dietary recall and 60 minute FFQ at each assessment time point, willingness to stay in touch with NEP educators, and no previous participation in NEP lessons within the last year.

The exclusion criteria only include not meeting the inclusion criteria.

Women who are pregnant will not be able to enroll in the study; however, once recruited, participants who become pregnant during the study period will be able to continue participating in the study.

The study population may be considered vulnerable because they are a low income and low resource population that may have a lower than average level of education. Precautions will be taken to minimize potential risks to the study population.

The maximum number of participants targeted for the study is n=800, n=400 in the control group and n=400 in the experimental group. Previous studies were used to calculate these estimates. Based on these "short term" studies, a 7% rate of attrition (n=17 out of 236) is expected to increase to approximately 40% (n≈320 of 800) in the proposed study due to the duration of 1 year between the post-assessment and the follow-up assessment. Based on these attrition considerations and our previous work, a sample size of n=800 will be the recruitment goal (control group n=400 and intervention group n=400) with an approximate final sample size of n=480 expected.

NEP educators will make no more than four coordinated efforts to remind participants of their participation in the study during the one year period between the second assessment and the final assessment. These attempts will also serve to update contact information, which NEP educators normally collect as part of their normal programming. Purdue researchers do not have access to participant names or home addresses. Purdue researchers only have participant names on consent forms and these documents are separated and stored separately from surveys. There is no way for researchers to identify participants or match their surveys with names. All participants in the study are also clients of the NEP Educators because they currently participate in the Nutrition Education Program as a participant in the intervention study group, or will participate at the conclusion of the study because they have indicated that they have the desire to participate as part of eligibility for the research study. The methods for contacting the participants include phone calls from the NEP educators, emails, physical flyers mailed to participants' home addresses, and a raffle. The email and physically mailed flyer will use the same content (attached). NEP educators will either email or physically mail the flyer, not both, depending on which method is preferred by the participant. All contact methods will be the same for control and intervention study group participants and are described below. Researchers will not directly contact participants unless the participant has requested telephone assistance to complete the dietary recalls and FFQ. Participants who have not completed the dietary recalls and FFQ in the amount of time provided will be called and asked if they would like to complete the dietary recalls and FFQ at that time over the phone, if they would like for researchers to resend the email link, or if they would like to make an appointment for researchers to call at a later time to complete the dietary recalls and FFQ over the phone. Participants will also be provided a Purdue telephone number for contacting researchers to complete the dietary recalls and FFQ.

Flyer:

- Flyers will include these components: thanking the participants for their participation, reminding them to update contact information with their NEP educator, information on an appropriate and free local event not related to nutrition or budgeting information in which the participants could take part, raffle information.
- NEP educators will either email the attached flyers to participants or physically mail the attached flyer to the participants' addresses they have on file.

Phone Call:

- NEP educators will call participants and update contact information, and either set an appointment to take the final survey or remind them of their appointment if already set

Raffle:

- Participants who complete the final survey before January 1st, 2017 will be entered into a $500 raffle. The odds of winning are approximately 1 in 480 and one $500 check will be awarded. The odds of winning may be updated on the study reminder flyer to reflect actual number of participants. The winner

will be randomly chosen by April 1st, 2017. If researchers are unable to contact the winning participant through their NEP Assistant after 3 attempts within one week (phone call, mailing, email), another participant will be randomly chosen. The winning participant may decline the $500. The winning participant's name, address, and social security number or taxpayer identification number will need to be shared with researchers at Purdue only if they win the raffle and only for dispersing the $500 check. The participant will also need to complete the Institutional Review Board Human Subject Receipt Log, which will be provided by the researchers. Non-resident alien recipients will have to complete information within the Glacier Tax Compliance software system (www.online-tax.net) to assess tax reporting and withholding requirements. This is explained in the consent form. Other than previously stated, no payment or additional action is required to enter the raffle. Participation in additional research or other consideration is not necessary. Void where prohibited or restricted by law. Subject to all federal, state, and local laws.

- The raffle will be advertised on the scheduled email and physically mailed flyers and through phone calls to participants.

Proposed Retention Tasks Timeline:

Month	Retention Task
January	• Email Flyer/ Mail physical flyer to home address
March	• Phone Call
May	• Email Flyer/ Mail physical flyer to home address
July	• Phone Call

D. RECRUITMENT OF SUBJECTS AND OBTAINING INFORMED CONSENT

NEP educators will recruit potential clients for the study. NEP educators will administer a screening survey to determine eligibility for the study. If potential participants do not wish to participate in the study or complete the screening survey, they may proceed with taking NEP lessons as usual without any effect on their relationship with the NEP, NEP educator, Extension, state or federal programs, or Purdue University. Study participants and non-participants may receive NEP lessons together without any effect on the study.

If a NEP client is eligible and willing to participate in the study, an informed consent form requiring their name and signature will be provided unless the IRB approves a waiver of signed consent, in which case NEP educators will explain the informed consent form to participants and allow them to read the consent form. If the consent form is provided electronically online, participants will be asked to select the "I agree" radio button to provide informed consent before proceeding to complete the survey. Participants will be provided their choice of an email or physical copy of the informed consent form.

NEP educators will facilitate data collection and use identification numbers to keep participant data together. NEP educators also collect private identifying information such as names, home addresses, email addresses, and telephone numbers for the NEP, but not as part of the study. The study investigators and co-investigators will receive the data with the participant identification numbers only and without any private identifying information. Researchers will be provided with only participant phone numbers and email addresses which will be linked only to participant identification numbers and never linked with participant names.

E. PROCEDURES FOR PAYMENT OF SUBJECTS

Study participants will be paid either in cash or through gift certificate to compensate them for the time they have spent in the study. NEP educators will provide participants $5 in cash for completing the first survey in person and a $10 gift certificate for completing the in person portions of surveys 2 and 3. Participants will receive a gift certificate of $15 for completing both the first dietary recall and FFQ and a $10 gift certificate for completing the second dietary recall at all 3 assessment time points. Participants may receive up to $30 for the first assessment and up to $35 for the second and third assessments.The gift certificate will be chosen by the participant from participating stores through an online gift certificate company and emailed to participants or mailed to participants' homes by the NEP educator, depending on the participant's preference. Participants could receive up to a monetary value of $100 for completing all three surveys.

F. CONFIDENTIALITY

NEP educators will keep a code key with participant names and participant ID numbers so that the surveys can be matched by participant ID number across assessment time points. They will keep this code key securely locked in a filing cabinet in their County Extension Office. NEP educators will be instructed to destroy the code key upon completion of the study. Only NEP educators will have access to their code key. The code key is attached.

Researchers will keep signed consent forms in a locked filing cabinet in the graduate student office of the Eicher-Miller lab in B-28 of Stone Hall. The consent forms will be kept for three years after the conclusion of study protocol. Researchers performing data entry, data analysis, and discussion of results will not have access to private identifying information. NEP educators may collect names but will be instructed to keep study data forms free from any identifiable information.

G. POTENTIAL RISKS TO SUBJECTS

Risks included in the study are no more than those encountered in everyday life.

To ensure that participants do not link their name with their identification number, NEP educators will be trained to remind participants not to write their names on any surveys. The NEP also does not collect names on the NEP Evaluation Tool used as part of usual NEP protocol, which will help maintain adherence to this study protocol.

H. BENEFITS TO BE GAINED BY THE INDIVIDUAL AND/OR SOCIETY

There are no direct benefits to the study participants. The benefits to society include a better informed understanding of the effects of SNAP-Ed on dietary quality, BMI, and food insecurity. This information could have policy implications such as providing more funding for the program, informing changes to the program or improvements to the program, and extending the reach of the program.

I. INVESTIGATOR'S EVALUATION OF THE RISK-BENEFIT RATIO

Since the risk to study participants is no more than that found in everyday life, and the benefits to society of the implications the study may have on policy and funding, the investigators conclude that the benefits far outweigh the risks.

J. WRITTEN INFORMED CONSENT FORM ***(to be attached to the Application Narrative)***

Written informed consent form is attached if signed consent is required by the IRB. Researchers request a waiver of signed consent.

K. WAIVER OF INFORMED CONSENT OR SIGNED CONSENT

Researchers are requesting a waiver of signed consent for individuals who prefer to complete all tasks including consent electronically; however, the individual will be present to complete the verbal consent process whether he/she signs the form or provides consent electronically. Participants will be provided the attached informed consent form after the being screened for study eligibility and before proceeding to complete the in-person survey. If participants complete the screening survey electronically through the Qualtrics application on the NEP educator's iPad, they will be required to provide informed consent by selecting the "I agree" radio button at the bottom of the informed consent form before proceeding to complete the survey. If participants complete the screening survey in paper form, then they will be provided an informed consent form that will not require a signature. All participants will be provided a copy of the informed consent form through their choice of email or a paper copy.

L. INTERNATIONAL RESEARCH

N/A

M. SUPPORTING DOCUMENTS ***(to be attached to the Application Narrative)***

- Consent Forms: 1. Signed Consent and 2. Informed Consent without signature
- Recruitment advertisement flyer
- Recruitment script

- Study reminder flyer to be emailed or physically mailed
- Instructions for height and weight measurements
- Participant Information Sheet
- Participant Code Key
- Email script and Phone call script for administering dietary recall and FFQ
- Survey instruments (Screening Survey, 18-item US Household Food Security Survey Module including characteristics questions for 3 time points, NEP medium term survey, Diet History Questionnaire II questions for past year and past month reference time periods)
- Supplemental Question (pregnancy status questions for use with paper surveys at time points 2 and 3)
- A link to the ASA24 (24-hour dietary recall) demonstration website can be viewed at https://asa24.nci.nih.gov/demo.aspx (Microsoft Silverlight must be installed if not already: http://www.microsoft.com/silverlight/).
- The official participant site link to the ASA24 can be viewed at https://asa24.nci.nih.gov.
- A link to the Diet History Questionnaire II (DHQ II) demonstration website can be viewed at https://appliedresearch.cancer.gov/cgi-bin/dhq2.pl?module=2&method=1