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RESEARCH TRIANGLE INSTITUTE
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
Request for Exemption from IRB Review

To request approval for exemption from Institutional Review Board (IRB) review, the Project Manager (includes Project Director or Leader, Principal Investigator, or Survey Manager) must complete this form and deliver the request to the an IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: 09/28/10

RTI Project No.: 0212343.001.005

Project Title: Models of SNAP-Ed and Evaluation, Wave II (Michigan State University Extension)

Project Manager: Sheryl C. Cates

Sponsor: U.S. Department of Agriculture's Food and Nutrition Service

Date Participation of Human Subjects Scheduled to Begin: 01/01/12

A. Brief Description of Study Procedures and Participant Population: RTI has been contracted by the U.S. Department of Agriculture's Food and Nutrition Service (USDA, FNS) to conduct an impact evaluation of the Eat Smart, Live Strong nutrition education intervention, which is being conducted by the Michigan State University Extension (MSUE) and aims to increase older adults' intakes of fruit and vegetables through four educational sessions. The purpose of the impact evaluation is to measure any changes in older adults' knowledge, attitudes, and behavior regarding nutrition.

The study population for the impact evaluation includes older adults aged 60 years old and older who attend one of 28 identified senior centers in nine Michigan counties. Fourteen senior centers will receive the intervention, while the remaining centers will be assigned to the control group. We will work with MSUE to coordinate the data collection for the pre-intervention survey at the intervention and control centers. MSUE will make the initial contact with treatment and control centers to encourage their participation in the study. One week before the first intervention session, study participants in the treatment and control groups will read and sign an informed consent form and complete the RTI impact evaluation questionnaire.

The questionnaire will be self-administered in a group setting. The pre-survey will take 15 minutes to complete, and respondents will receive $10 for completing the pre-survey. Additionally, RTI field interviewer will collect contact information from respondents in order to contact them by mail or telephone for the post-survey. RTI field interviewers will enter respondents' contact information into an electronic template, encrypt the data, and email it to RTI. Field interviewers will ship the hardcopy contact forms and completed surveys to RTI's main office via FedEx on a weekly basis. Once the forms arrive at RTI's main office, the contact information will be verified and the forms will then be shredded. The survey data will be entered into an electronic database at RTI, and the surveys shredded at the end of the study.

For the post-survey, we will mail a pre-notification letter the last week of the intervention to all study participants, then mail the post-survey one week after the end of the intervention. Respondents will be instructed to return their completed survey in the included self-addressed postage paid return envelope to RTI, where the surveys will be entered into an electronic database. Within 5 days, we will send a postcard to remind participants to complete the survey. One week later, we will make a minimum of ten call attempts to nonrespondents to see if they would prefer to complete the survey over the phone. The telephone surveys will be CATI and conducted by RTI interviewers. The post-survey will collect the

same information as the pre-survey, plus information on intervention dosage (e.g., receipt of program) and program satisfaction from participants in the intervention group. The post-survey will take 18 minutes to complete, and participants will receive $15 for completing the post-survey. The surveys will be shredded at the end of the study.

MSUE is conducting a separate evaluation with pre- and post-surveys using a separate consent form. MSUE is collecting information on participant demographics in the presurvey. To avoid asking respondents to provide this information twice (once in the RTI survey and once in the MSUE survey), MSUE plans to provide RTI this demographic data. The data will be transported electronically via our secure, password protected FTP site and linked to the RTI survey data.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: There are minimal psychological, social, or legal risks to participating in the study. It is possible that participants' answers to survey questions may be seen by other participants or household members if they do not take precautions to keep their answers confidential when completing the pre- and post-surveys, resepectively; however, we are not collecting information that is sensitive in nature. Participation in the study is completely voluntary, and individuals can stop participating at any time and receive payment for the parts of the study completed to date.

Each participant will be assigned a unique ID number after their contact information is received. We will develop and maintain a link file with the participants' ID number, names, and contact information. Once this information is entered into the file, we will shred all hardcopies. Participants' answers to survey questions will be stored separately so that their names and contact information will not be stored with their survey responses. At the end of the study, we will destroy the electronic copy of participants' contact information. No participant names or identifying information will be used in any reports.

C1. For educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview research with adults:

1. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

   [x] Yes [ ] No [ ] NA

   If yes, explain:

   Each participant will be assigned a unique ID number. We will develop and maintain a link file with the participants' ID numbers, names, and contact information. Participants' answers to survey questions will be stored separately from identifying information.

2. Would any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing employability or reputation?

   [ ] Yes [x] No [ ] NA

C2. For research with existing data, documents, records, pathological or diagnostic specimens:

1. Are the sources of the data publicly available?

   [ ] Yes [ ] No [x] NA

   If no, explain:

2. Is information recorded in such a manner that human subjects can be identified, directly *or through identifiers linked to the subjects?*

☐ Yes ☐ No ☒ NA

If yes, explain:

D. Describe other categories of exempt research[1] here: _____

_____

[1] Note: Categories C1 and C2 above are the most common types of research conducted at RTI that may be exempt from IRB review. For a complete list of exemption criteria, please see below.

----------Space below this line for IRB use only.----------

Decision of IRB Coordinator or Chair

Name of IRB Coordinator or Chair making exemption determination: David Borasky

Please check appropriate answer(s):

I agree that this study is exempt [45CFR46.101(b)] from IRB review based upon the information provided by the Project Manager above. (Check applicable category below.)

__(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

X_(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

__(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

__(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

__5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

__(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

_____ 09-29-2010

Signature of IRB Coordinator or Chair named above Date

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