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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: 09/07/10

RTI Project No.: 0212343.001.005

Project Title: Models of SNAP-Ed and Evaluation, Wave II (University of Kentucky Cooperative Extension Services)

Project Manager: Sheryl C. Cates

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

Date Participation of Human Subjects Scheduled to Begin: 09/01/11

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 LEAP2 nutrition education intervention, which is being conducted by the University of Kentucky Cooperative Extension Services (UKCES) and aims to increase first through third grade students' intakes of fruit and vegetables by using family newsletters, children books, and food tastings at school. The purpose of the impact evaluation is to measure any changes in parents' knowledge, attitudes, and behavior regarding nutrition.

The study population for the impact evaluation includes parents of first through third grade students enrolled in 10 schools in Laurel County and six schools in Perry County. Five schools in Laurel County and three schools in Perry County will receive the intervention, while the remaining schools will be assigned to the control group. We will work with UKCES and the schools to coordinate the data collection. UKCES will make the initial contact with schools to encourage participation, and RTI field interviewers will contact school principals and teachers as appropriate to discuss study procedures and get buy-in. Further, we will offer the school a cash incentive of $250 to assist with the study. We will ask teachers to send home with their students an invitation for parents to participate in the study (see appendix A for study communications). On the informed consent form, parents/caregivers will be asked to indicate whether they are willing to participate in the study and, if so, provide their contact information. Whether or not they agree to participate in the study, parents/caregivers will be instructed to return the form in the provided envelope to their children's teachers. Teachers will be asked to track the sealed envelopes and distribute a token incentive worth $1.00 (e.g., friendship bracelet, pencil) to the children who return an envelope. To acknowledge their assistance, we will provide classroom teachers a cash incentive (up to $25) based on the percentage of students who return an envelope, not the number of parents/caregivers who enroll. Site coordinators assigned by the school principals will be asked to collect the sealed envelopes for pick up by a RTI field interviewer on a daily basis and will receive $50 for their assistance. RTI field interviewers will enter cooperating parents/caregivers' contact information into an electronic template, encrypt the data, and email it to RTI on a nightly basis. Field interviewers will ship the hardcopy forms 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. Once the forms are received, the data collection process will begin.

We will mail to parents for whom we received contact information a pre-survey with a cover letter offering a monetary incentive for completing the pre-survey, which will collect information on their children's intake of fruits and vegetables (see Appendix B for questionnaires). 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. Within one week, 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 pre-survey will take 12 minutes to complete, and respondents will receive $10 for completing the pre-survey. We will follow a similar approach for conducting the post-surveys, except that we will mail a pre-notification letter to all participants the last week of the intervention. Telephone contact of nonrespondents will begin a week after the second mailing with a minimum of ten call attempts made to each working phone number. The post-survey will also collect the same information as the pre-survey, plus information on intervention dosage (e.g., receipt of program take-home materials) and program satisfaction from participants in the intervention group. The post-survey will take 14 minutes to complete, and participants will receive $15 for completing the post-survey.

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 household members if they do not take precautions to keep their answers confidential when completing the survey; 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 identify 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.

_____ 09-28-2010

Signature of IRB Coordinator or Chair named above Date

Version 11-30-00