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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 an IRB Administrator. The Project Manager will be notified if more information is necessary and the results of the determination.

Date: 11-28-11 RTI Project/Proposal No.: 0211965.028.000.001/ 0281101.035

Project Title: **National Evaluation of Comprehensive Health Programs to Address Physical Activity, Nutrition, and Tobacco Use in the Workplace**

Project Managers: Jim Hersey and Laurie Cluff Sponsor: CDC

Date Participation of Human Subjects Scheduled to Begin: March 2012

A. Brief Description of Study Procedures and Participant Population

CDC has funded an implementation contactor to lead 70-100 businesses through the process of building a core workplace health program, referred to as CDC's National Healthy Worksite (NHW) program. The businesses will be grouped into approximately 7 geographically-based communities. The NHW Program is designed to assist employers in implementing science and practice-based prevention and wellness strategies that will lead to specific, measureable health outcomes to reduce chronic disease rates. The implementation contractor will obtain informed consent and collect biometric, health behavior, and health attitude data from employees before and after the workplace health programs are implemented. The implementation contractor will also collect data at the employer level related to organizational culture and the availability of health and wellness resources at and near the worksite. Finally, the implementation contractor will collect aggregate –level administrative data from the employer such as absenteeism and injury rates.

RTI has been awarded contract to conduct the national evaluation of the NHW program. As the national evaluator, RTI will conduct a process and outcome evaluation across all of the participating worksites. We will obtain process data from the implementation contractor including descriptive information about the worksites, worksite and employee recruitment techniques, length of time required to start worksite programs, specific wellness components implemented at each worksite, number of employees that participated, barriers to program implementation, and strategies for overcoming barriers. As part of our outcome evaluation, we will use de-identified employee level data collected by the implementation contractor including biometrics and health behaviors and attitudes.

To supplement our process and outcome evaluations, we will also develop several case studies. For the case studies, we will identify 7 to 10 employers who are willing to participate as case study subjects and who represent different communities, different industries, and different employee population characteristics. Case studies will be conducted to gain insight into the factors and variables that facilitate or hinder the successful implementation and outcomes of worksite health promotions programs.

To inform the national process evaluation and the case studies, we have developed discussion guides (see **Attachment A**) to collect information from individuals in the following roles:

- **Community Directors** (7-10 Implementation contractor staff members): These individuals will oversee the NHW activities at the 10-15 worksites included in the community they direct. We will conduct small group discussions, via telephone or in-person, with these individuals during their regularly scheduled group meeting times whenever possible. These discussions will focus

on employer engagement and retention, and organizational level changes. We will hold these discussions at 6, 12, 18 and 24 months.

- **Health Coaches and Nutrition Coaches** (20 Implementation contractor health and nutrition coaches). The health and nutrition coaches will work with employees at individual worksites to develop worksite programs and individual wellness plans. We will conduct interviews or small group discussions with these individuals, via telephone, during their regularly scheduled group meeting times whenever possible. These discussions will focus on employee participation, strategies for encouraging behavior change and success stories. We will hold these discussions at three months after the start of the program and again at approximately 18-20 months.
- **Employer Steering Committee Members**: From among the 7 to 10 worksites selected for the case studies, we will invite 1 to 3 staff members who served on the health program steering committee to discuss their experiences. We will obtain contacts from the implementation contractor. We will conduct these discussions via telephone with individuals or small groups from a single worksite. These discussions will focus on challenges and strategies for successful program implementation and sustainment. We will hold these discussions at month 20, near the end of program implementation.
- **Employer Wellness Committee Members**: From among the worksites selected for the case studies, we will invite 2 to 5 staff members who served on the health program wellness committee (or served as program champions) to discuss their experiences. We will obtain contacts from the implementation contractor. We will conduct these via telephone with individuals or small groups from a single worksite. These discussions will focus on their opinions about programming and workplace changes. We will hold these discussions at month 20, near the end of program implementation.

The implementation contactor will set up times during the community directors' and health coaches/nutrition coaches' regularly scheduled meetings for RTI to join the call and conduct discussions. The NHW program implementation contactor will collect contact information from employer steering committee members and employer wellness committee members who are interested in participating in discussions. RTI will contact interested individuals to schedule a time and provide call-in information for the telephone discussions.

In addition to discussions, RTI will also conduct four web surveys. First, we will conduct a short web-based survey of a random sample of employers (see **Attachment B**) who were invited to participate in the NHW, but did not participate. We will draw a simple random sample of non-participating employers who were on the implementation contactor's list of employers to contact. We will sample approximately 30 employers from each community area. The purpose of the survey of non-participating employers is to determine if there are any systematic differences, such as size or industry, between employers who agreed to participate and those who declined. The survey will ask about current workplace health promotion programs and reasons for not participating in the NHW. This survey will be administered approximately 2 months after the conclusion of the recruitment effort in each community area.

Second, we will conduct a short web-based follow-up survey of participating NHW worksites (see **Attachment C**) to provide information about program maintenance and sustainment. We will administer the survey to a representative for each employer (contact provided by the NHW implementation contractor), such as the wellness committee champion or human resources staff, approximately 8 months after the formal program implementation ends. The purpose of this survey is to determine to what extent each employer is continuing to implement the NHW program elements, what changes have been made, what barriers have been encountered, and what lessons were learned.

Finally, we will conduct two brief web-based surveys of employers who participated in training sessions offered through the program (see **Attachment D**). Employers who participate in the NHW program and other employers within the same communities as the participating employers are eligible to participate in four in-person worksite health promotion training sessions offered by the implementation contractor. We have developed a two-part survey to evaluate the employers' perceptions of the usefulness and effectiveness of these training sessions. Training Survey Part 1 will be sent to employers who participate in at least one of the first 3 training sessions and will be administered 2 months after the third training sessions. Training Survey Part 2 will be sent to employers who participate in the fourth training session and will be administered 2 months after the fourth session is delivered.

We will email the individuals selected to complete the surveys a link. We will set the survey software on an "anonymous" setting, meaning respondents names or other identifying information such as email addresses or IP addresses will not be saved with their responses. About a week after the survey link has been sent to participants we will email them a reminder to complete it (see **Attachments E, F, & G**). After another week, we will call participants to remind them to complete the survey.

B. **Description of Physical, Psychological, Social or Legal Risks to Participants** There are minimal psychological, social, or legal risks to participating in this study. Participants will be sharing their thoughts and opinions about their experience with the NHW program, but no sensitive information will be asked of participants. Participation is voluntary, and respondents can choose not to answer any of the interview or survey questions.

During the discussions/interviews with employer representatives, we will ask participants to use their first names only. Although worksite names may be discussed by participants, this information will not be linked to the respondents' identity in reports. In reports or other information provided to CDC, we will protect the identity of worksites unless they explicitly give us permission to identify them by name. Project staff will take notes during discussions, but these discussions will not be audio or video recorded.

Regarding the web surveys, respondents' names or other identifying information will not be collected.

Regarding employee-level health, behavioral, and attitude data, information provided by the implementation contractor or employers will not be identifiable.

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: Participants from worksites (employer steering committee members and employer wellness committee members) will use their first names in discussions and may choose to say the name of their employer. Although the session will not be audio recorded, project staff will take notes during discussions and may record a participants' first name. However, when these notes are entered in a project database, participants' first names will not be stored with their responses. After entering notes in the database, all other notes will be shredded. Employers' or worksites' names will only be recorded and reported if they have given us permission to identify them by name.

Implementation contractor participants (e.g., community directors and health/nutrition coaches) will use their first names in discussions. Sessions may be audio-recorded, and project staff will take notes during discussions and may record a participants' first name. However, when these notes are entered in a project

database, participants' first names will not be stored with their responses. After entering notes in the database, all other notes and recordings will be destroyed.

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 ☒ No ☐ NA

If yes, explain

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

1. Are the sources of the data publicly available?

☐ Yes ☐ No ☒ 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: Juesta Caddell, Ph.D.

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.

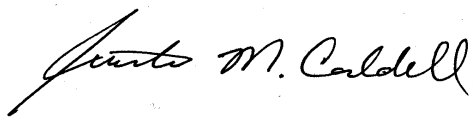
__(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed

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.



Signature of IRB Coordinator or Chair named above

04-19-2012
Date

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