IRB ID Number: 11436

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: February 12, 2010 **RTI Project/Proposal No.:** 0211829 (IRB ID #11436)

Project Title: Effectiveness and Implementation Trial of the Safe Dates Program

Project Manager: Olivia Ashley **Sponsor:** Centers for Disease Control and Prevention

Date Participation of Human Subjects Scheduled to Begin: 3/1/10

A. **Brief Description of Study Procedures and Participant Population:** This study aims to evaluate the effectiveness, implementation, and cost of the Safe Dates adolescent dating violence prevention program. IRB approval for the main study data collection was provided 5/1/07. This Centers for Disease Control and Prevention (CDC) funded project also involves conducting qualitative research about Safe Dates modification/adaptation needs in urban schools. Teachers who have taught Safe Dates will participate in interviews about the Safe Dates program to find out their opinion on the Safe Dates program and whether they think the Safe Dates program should be modified or adapted for urban schools (teacher interview script is attached). This application seeks permission to conduct interviews (either group or individual) with teachers in urban schools about the Safe Dates program.

   Lead letters will be sent to a subset of schools in the main study to contact teachers for the interviews. Teachers at these schools who taught Safe Dates will be sent a lead letter (both school lead letter and teacher lead letter are attached) requesting their contact information (teacher contact information form is attached) so RTI staff can set up a phone or in-person interview during the summer. We will seek verbal consent from all teachers for their participation in the interviews. Depending on scheduling and availability, we expect to conduct up to 20 teacher interviews. Individual interviews will last approximately 60 minutes. Group interviews, each lasting 90 minutes, may be conducted when multiple teachers at one school prefer to be interviewed together instead of separately. All interviews will be audiotaped and conducted by a team of two researchers: one to lead the interview and the other to serve as coordinator and note taker. The audiotapes will be sent to a company in Asheville, NC, to be transcribed. Once all interview transcripts have been typed, audiotapes of the interviews will be destroyed.

B. **Description of Physical, Psychological, Social or Legal Risks to Participants:** There are no anticipated physical, psychological, or social risks to respondents. The interview guides will ask teachers about their opinions about the Safe Dates program, whether they believe it is relevant to their community, and whether they recommend changes for urban settings. Teachers will be told the interview will be audiotaped and are free to not participate or discontinue the interview if they do not want to be audiotaped. Participants will be asked to indicate if there are any statements they made during the interview for which they prefer not to be cited by name, school or school district. We will not ask respondents about individual students participating in the Safe Dates program.

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: **We will not ask teachers for sensitive information about themselves or individual students participating in the Safe Dates program at their school. Teachers will be asked to indicate if there is any statement they made during the interview or group session for which they prefer not to be cited by name, school name, or school district.**

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

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 [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 [X] 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.

Signature of IRB Coordinator or Chair named above

February 15, 2010
Date

Version 11-30-00