From: Galusha, Pamela (CDC/OD/OCSO)
Sent: Monday, May 08, 2006 3:01 PM
To: Cleveland, Jennifer L. (CDC/NCCDPHP/DOH)
Cc: Redmond-Leonard, Joan A. (CDC/NCCDPHP/OD)
Subject: 4873: Approval of Exemption

Follow Up Flag: Follow up
Flag Status: Flagged

I have reviewed the request to exempt protocol 4873, "Evaluation Channels for Dissemination and Influencing Factors for Implementation of CDC's Dental Infection Control Guidelines." I find that this research activity is exempt under 45 CFR 46.101(b)(2). Changes to this protocol may not be implemented until they are reviewed and determined to be consistent with the exemption categories. You will be asked in one year (by 05/07/07) to confirm that no changes have occurred in the protocol or the related science that would affect the ethical appropriateness of the research or this exemption. Please be advised that the investigators remain responsible for appropriate human research protections even for research that is exempt from regulations for protecting human subjects.

Pam Galusha
Lead IRB Administrator
CDC Human Research Protection Office

IRB ID: 11557

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: April 6, 2006 **RTI Project/Proposal No.:** 0208235.045

Project Title: Evaluating Channels for Dissemination and Influencing Factors for Implementation of CDC's Dental Infection Control Guidelines

Project Manager: Arthur Bonito **Sponsor:** CDC

Date Participation of Human Subjects Scheduled to Begin: July 2006

A. Brief Description of Study Procedures and Participant Population: We will conduct a mail survey of a probability sample of 6,500 private practice dentists. The ADA will select the sample according to RTI specifications and conduct survey using an RTI-developed instrument.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: None (see attached questionnaire).

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: **Identification numbers linked to dentists for purpose of survey follow-up and data processing, then the linkage 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 [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 ☐ 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: Nancy Berkman, PhD

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

March 6, 2006
Date

Version 11-30-00