Copy of RTI International IRB Exemption Determination

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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: 01-26-07 **RTI Project/Proposal No.: 0208633.006**

Project Title: Economic Analysis of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

Project Manager: Sujha Subramanian **Sponsor:** Centers for Disease Control and Prevention Division of Cancer Prevention and Control Atlanta, GA

Date Participation of Human Subjects Scheduled to Begin: N/A

A. Brief Description of Study Procedures and Participant Population: The NBCCEDP is the largest organized cancer screening program in the United States but to date there has been no systematic analysis of the economic costs incurred by the program. CDC is proposing to collect one year of cost data, (period covering 07/01/2005—06/30/2006), from all the 68 NBCCEDP grantees to assess the cost and cost-effectiveness of the program. The cost data provided by the 68 grantees will be used to evaluate the programs to ensure the most appropriate use of limited program resources. Performing an assessment of the resources expended on NBCCEDP will provide valuable information to the CDC and its' partners for improving program efficiency within the various components of the NBCCEDP including screening, case management, outreach, and overall management. The cost data will allow CDC to assess the costs of the various program components, identify factors that impact average cost, perform cost-effectiveness analysis and develop a resource allocation tool. The collection and analysis of the cost data will allow CDC to utilize a more systematic process to allocate program resources based on grantees' past performance, level of efficiency, and future needs.

B. Description of Physical, Psychological, Social or Legal Risks to Participants: N/A

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?*

   [ ] Yes [ ] No [X] NA

   If yes, explain:

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 [X] 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:

We are collecting program level data which does not contain any personal level information. The only information collected will be cost and other program specific data elements. This research does not involve collection of any patient level data.

[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.

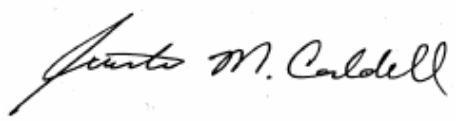
_ _(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers 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.

X (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

January 30, 2007
Date